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(54) **COLLAPSIBLE PROSTHETIC HEART VALVES**

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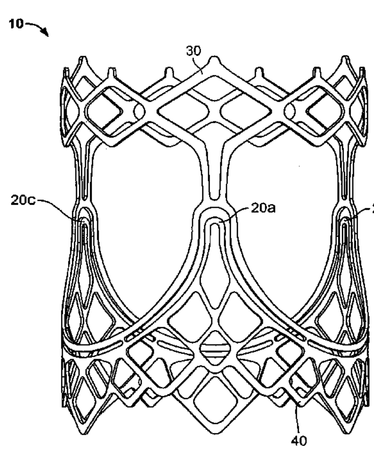
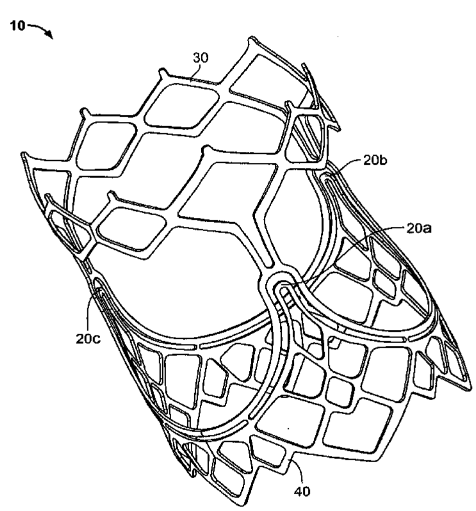
(57) **ABSTRACT**

Prosthetic heart valves, which are collapsible to a relatively small circumferential size for less invasive delivery into a patient and which then re-expand to operating size at an implant site in the patient, include a collapsible/expandable stent-like supporting structure and various components of flexible, sheet-like material that are attached to the supporting structure. For example, these sheet-like other components may include prosthetic valve leaflets, layers of buffering material, cuff material, etc. Improved structures and techniques are provided for securing such other components to the stent-like supporting structure of the valve.

6 Claims, 69 Drawing Sheets





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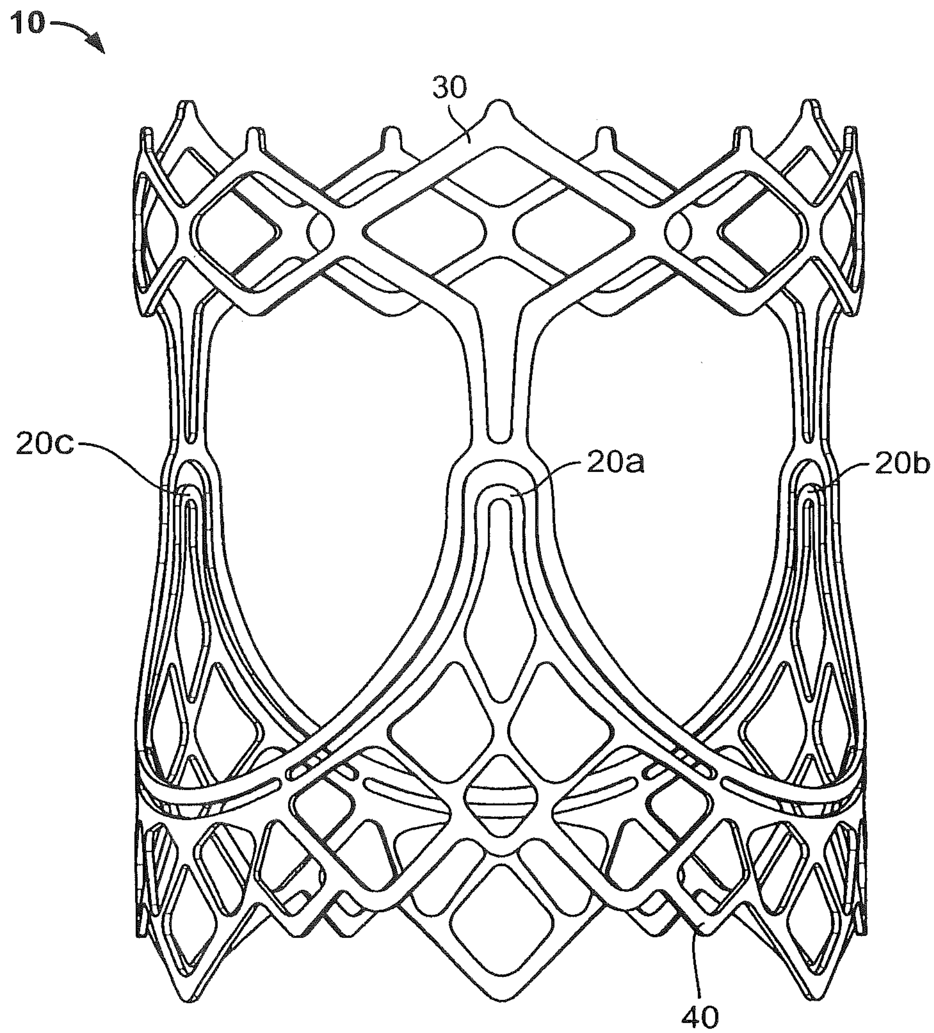

FIG. 1A

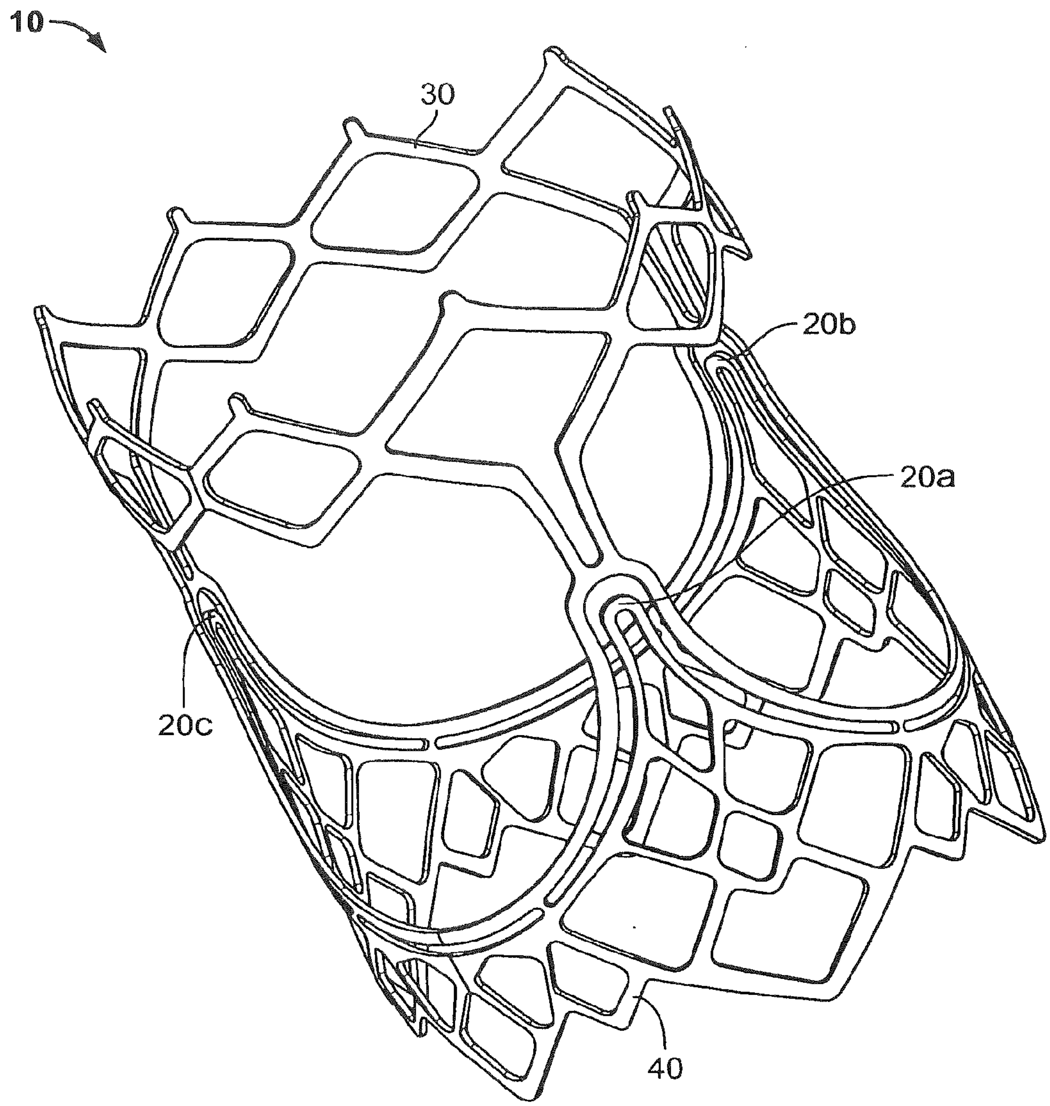

FIG. 1B

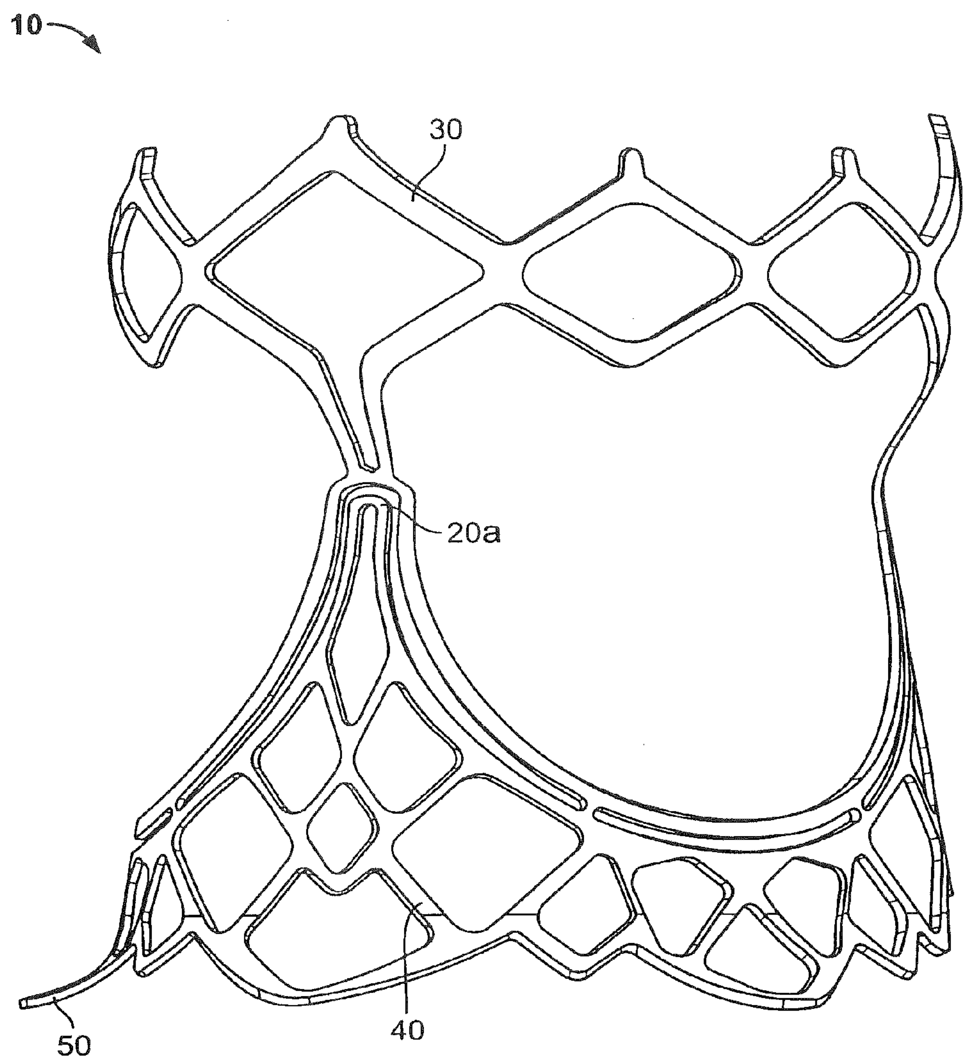

FIG. 2A

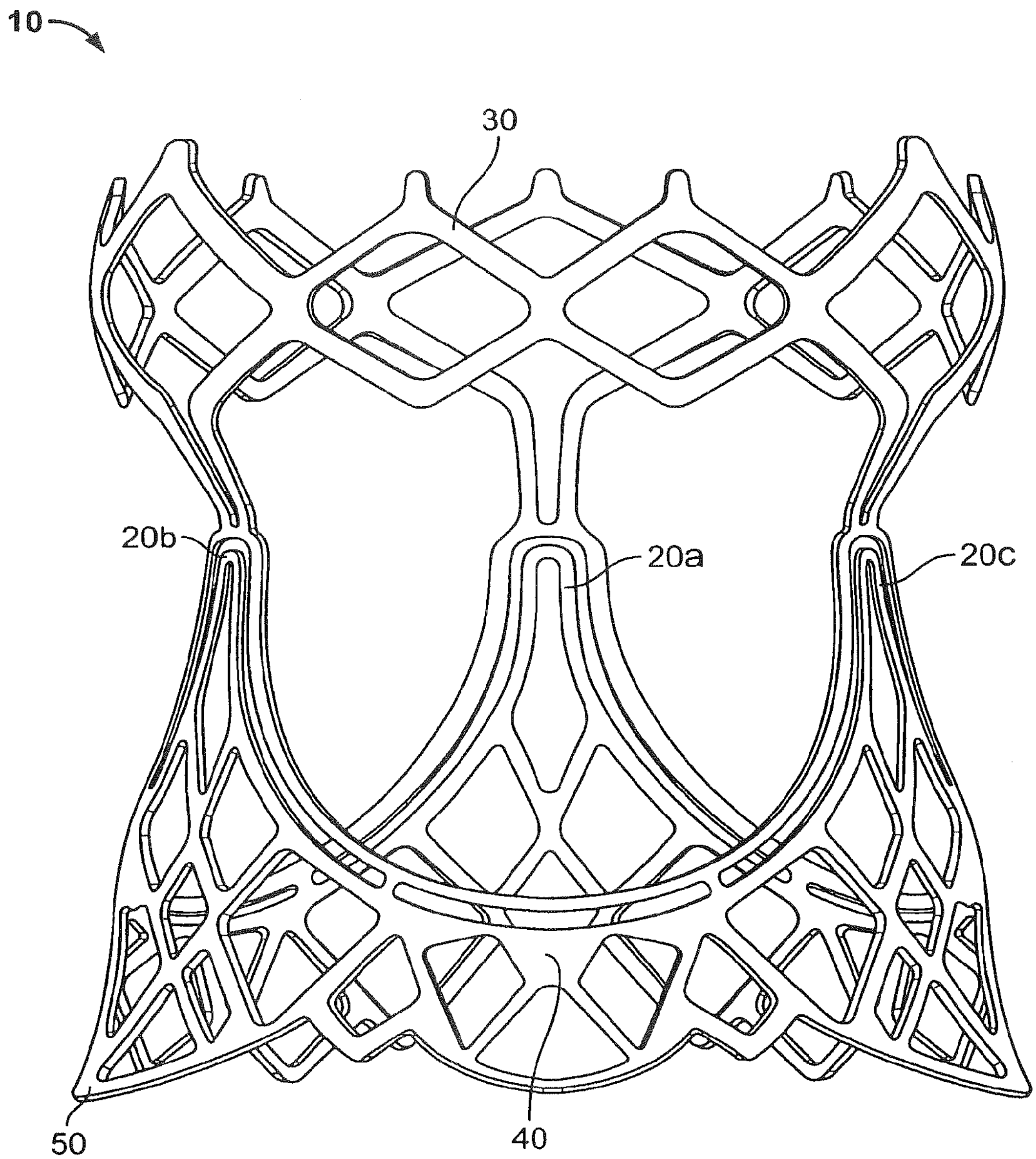

FIG. 2B

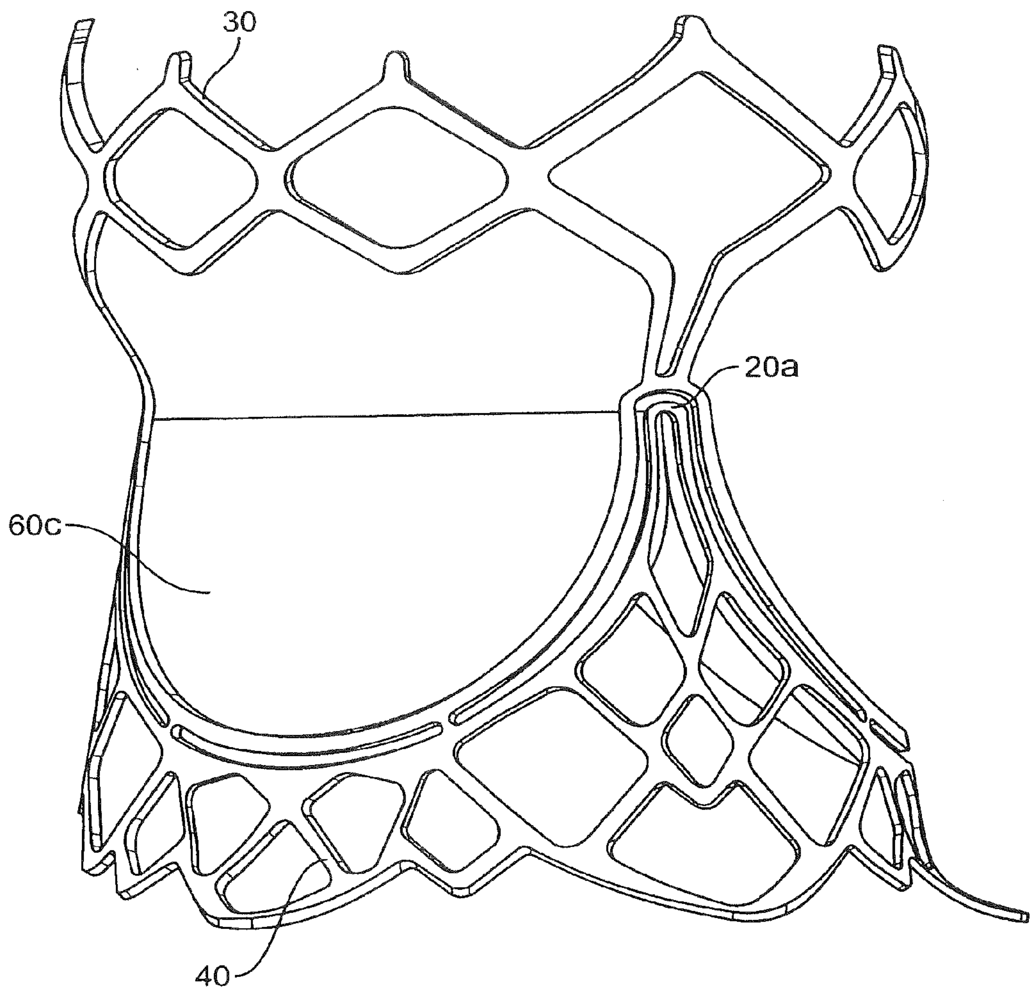

FIG. 3A

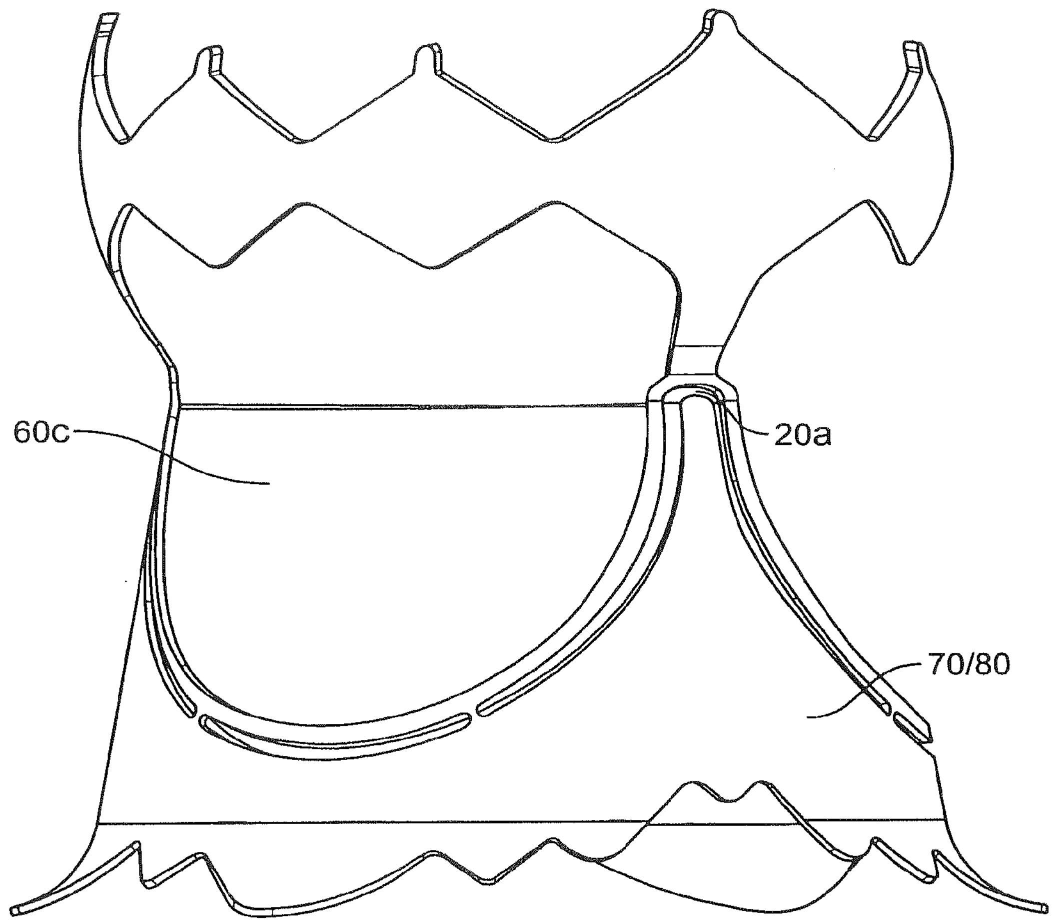

FIG. 3B

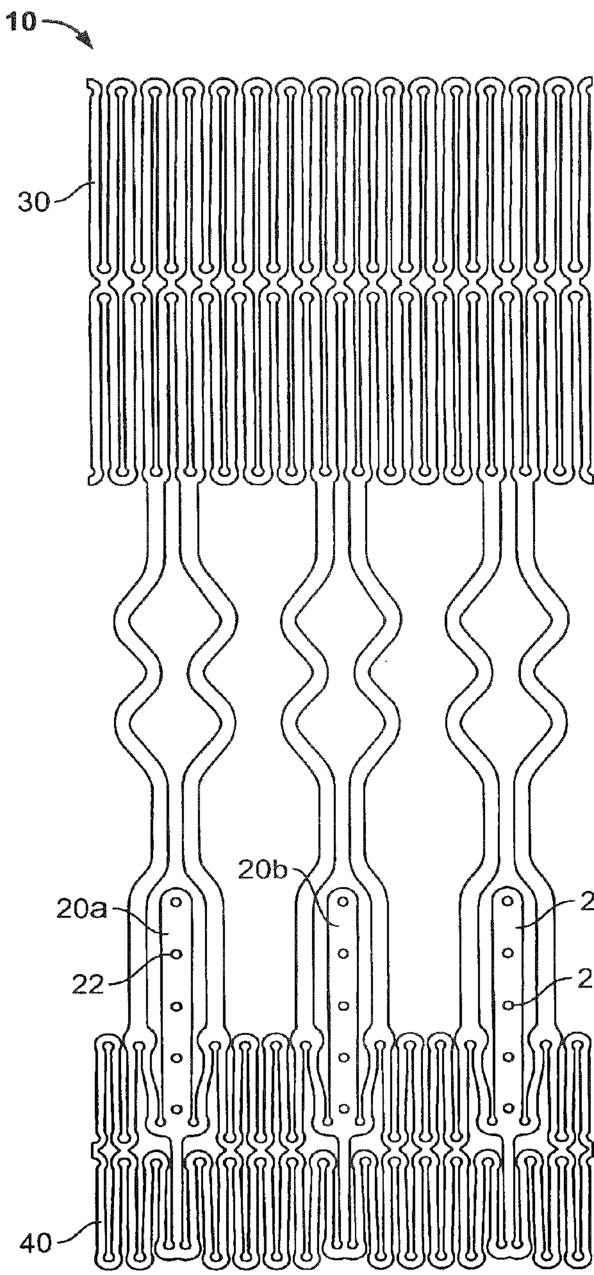

FIG. 4A

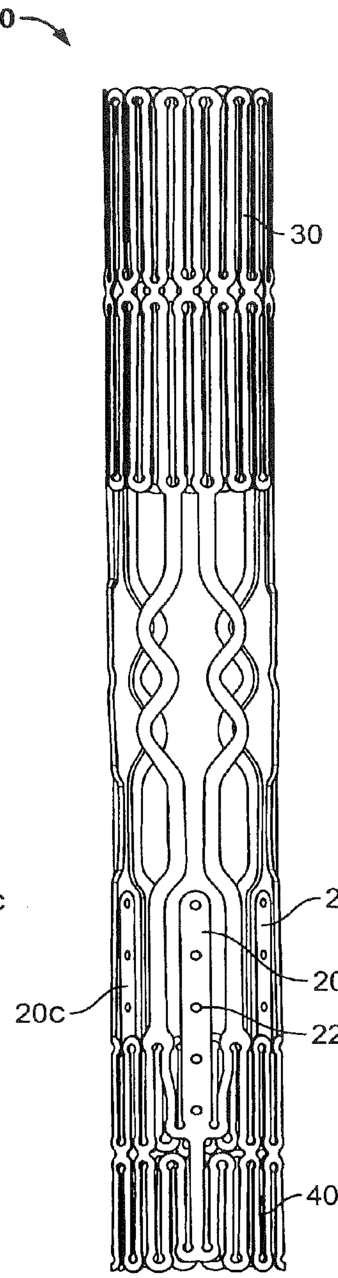

FIG. 4B

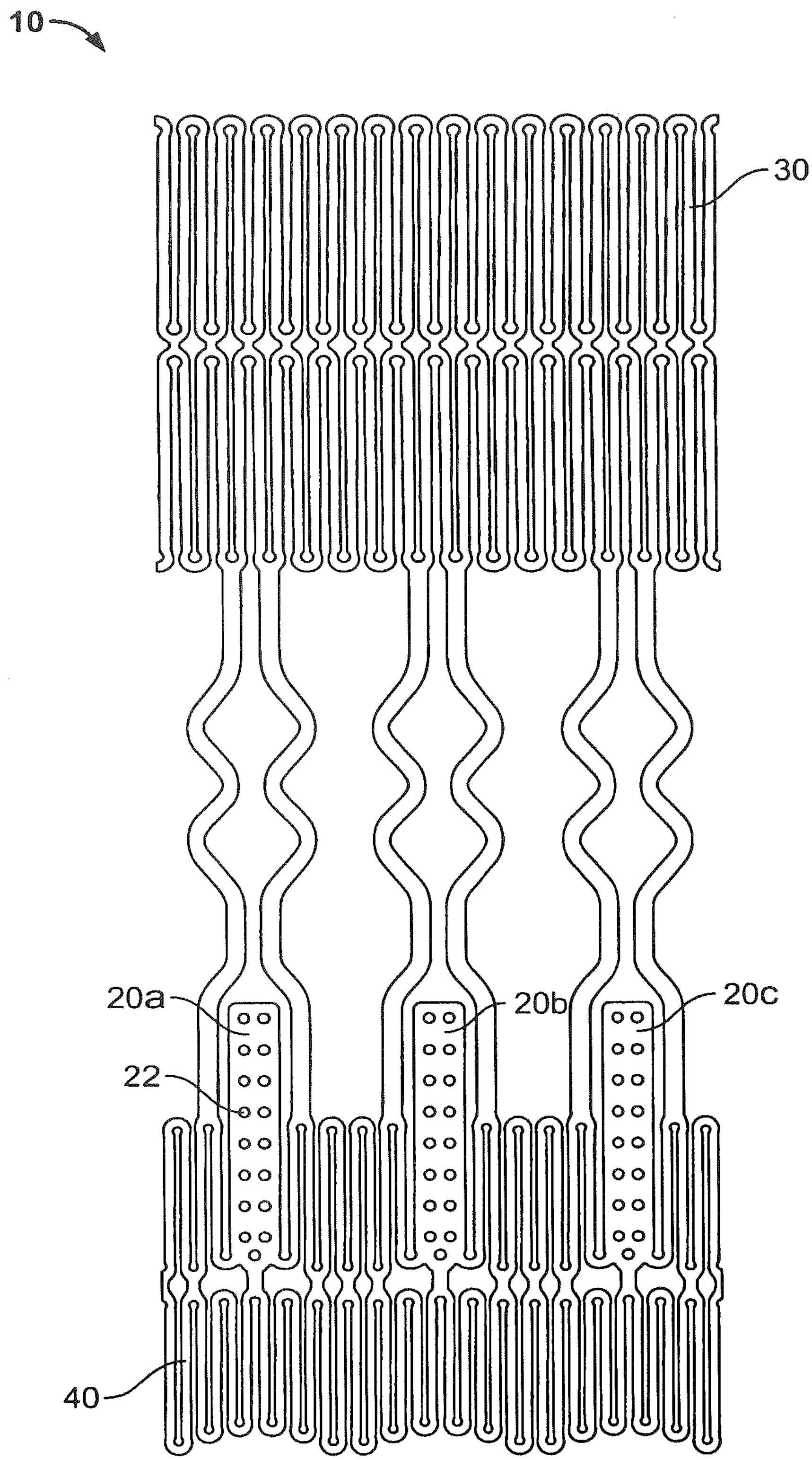

FIG. 5A

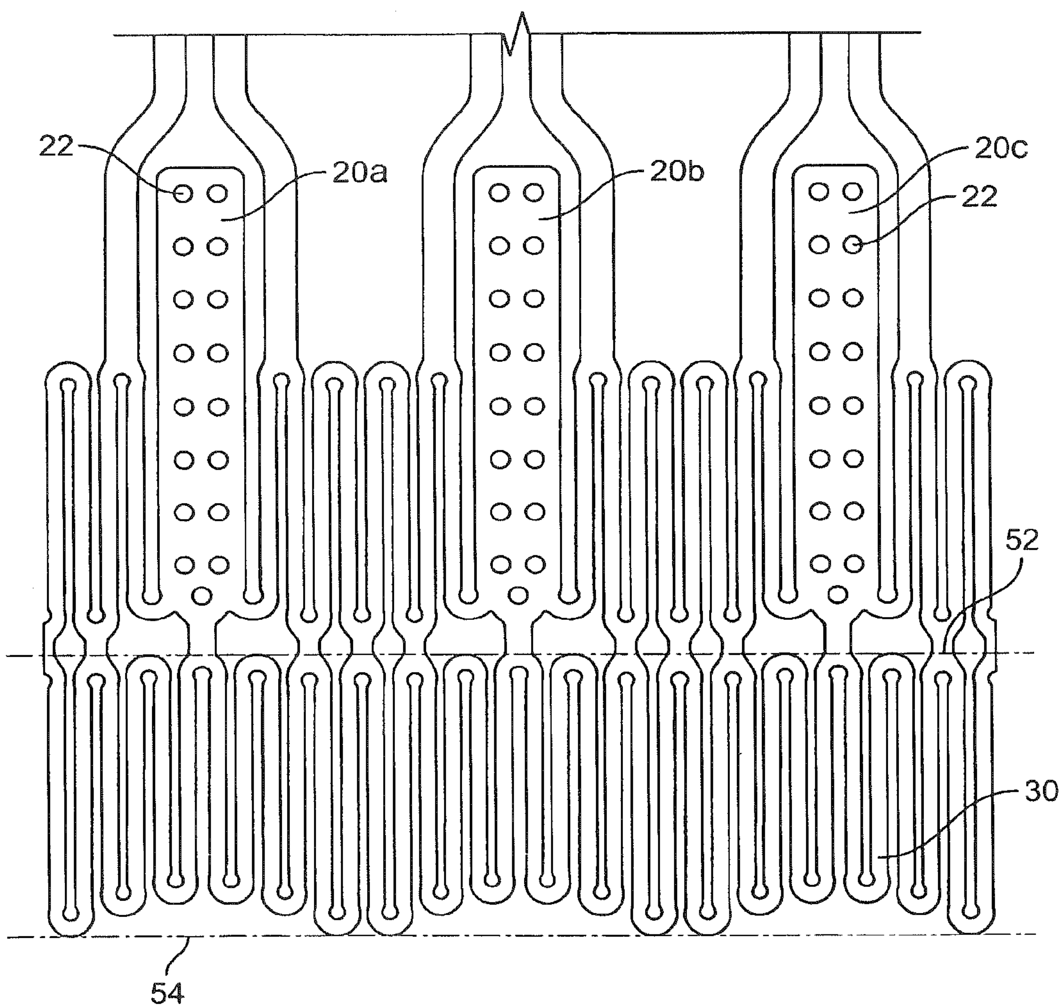

FIG. 5B

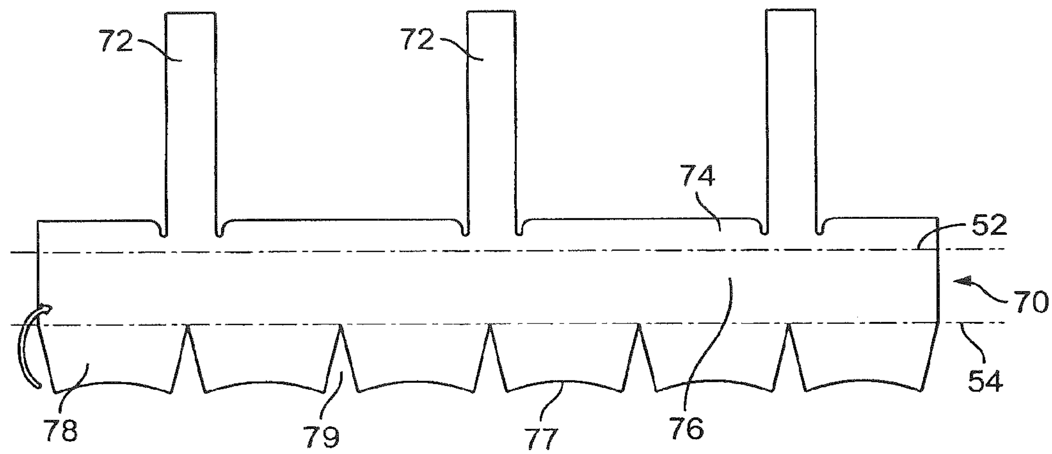

FIG. 6

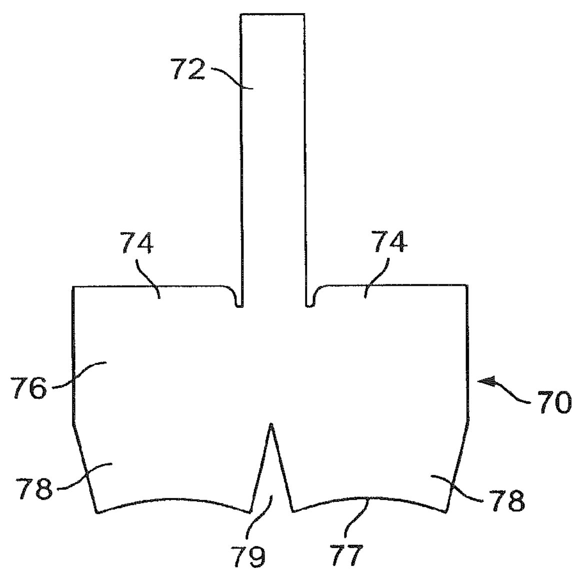

FIG. 7

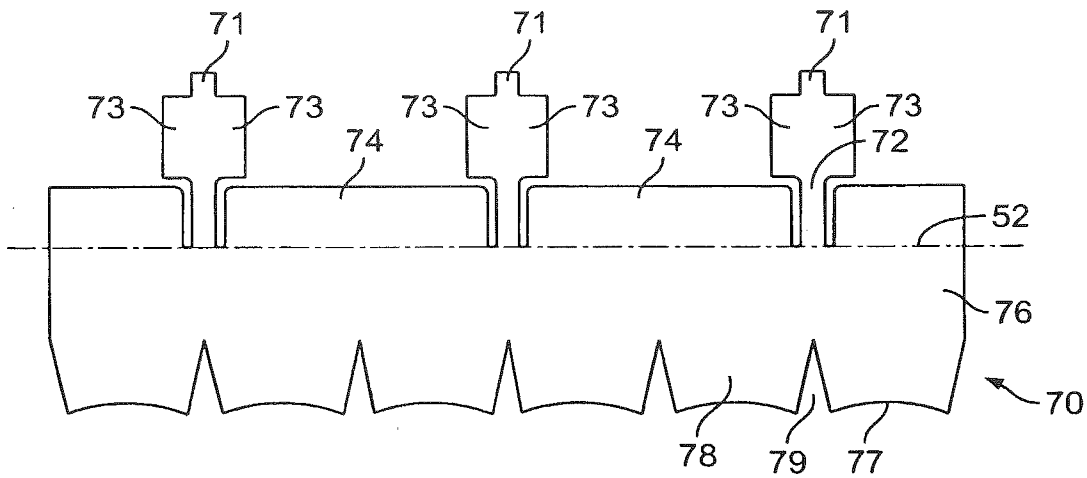

FIG. 8

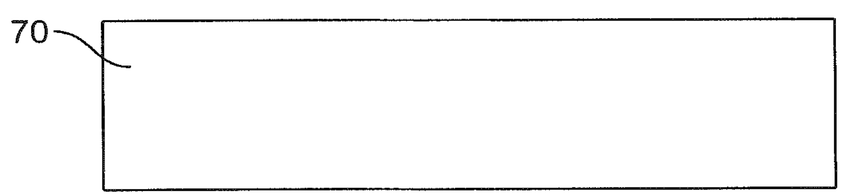

FIG. 9

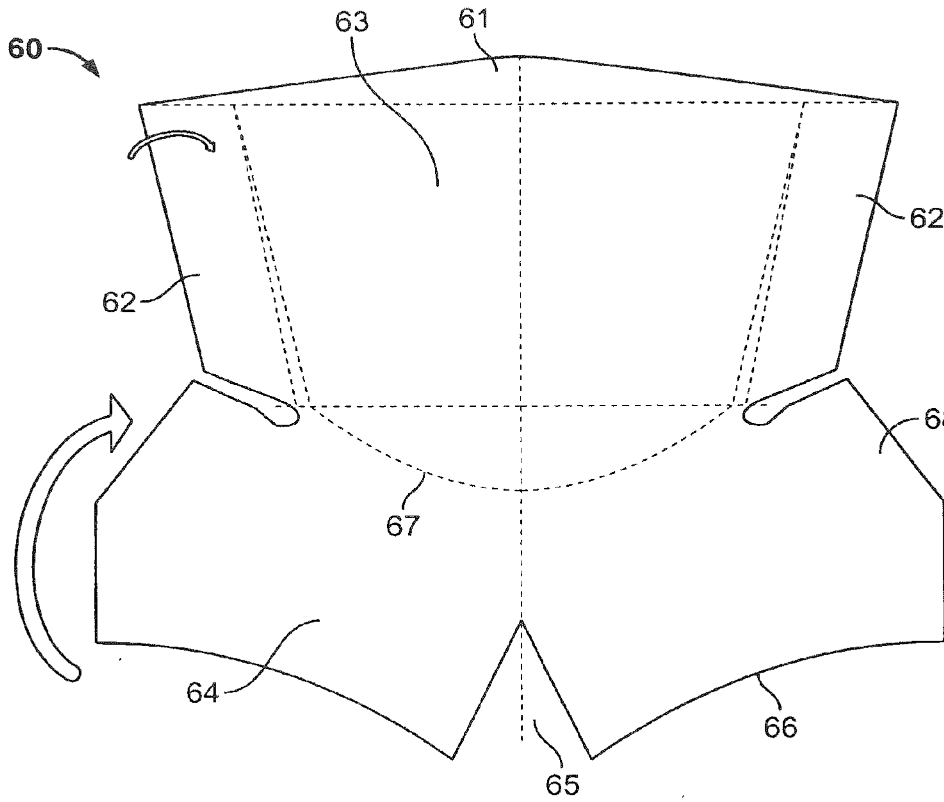

FIG. 10

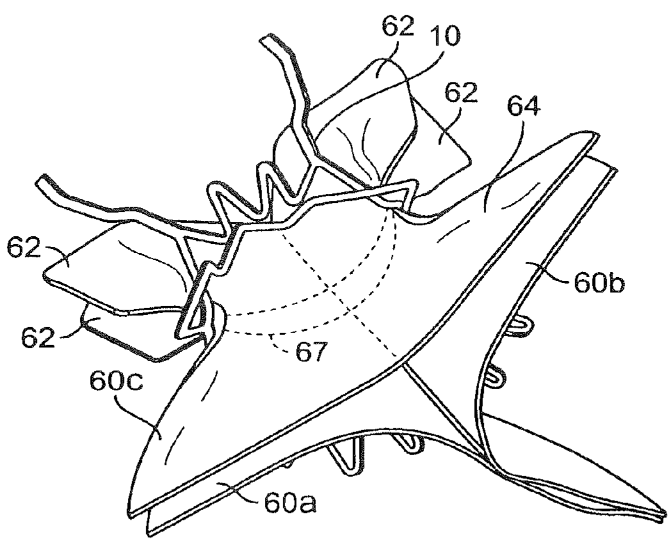

FIG. 11

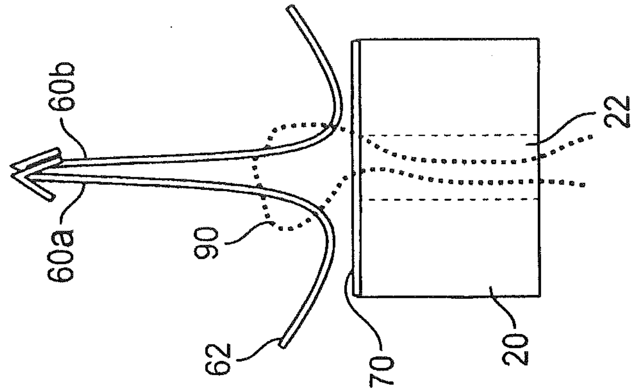

FIG. 12A

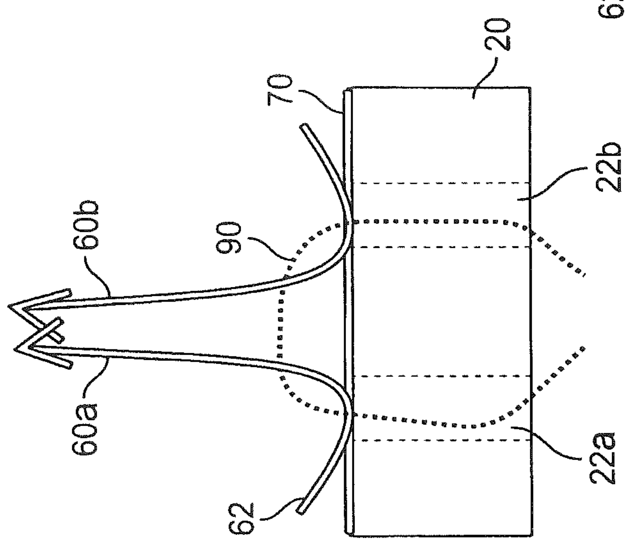

FIG. 12B

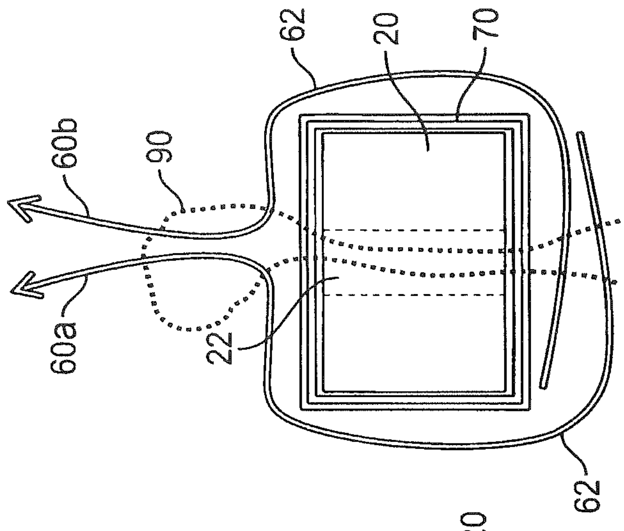

FIG. 12C

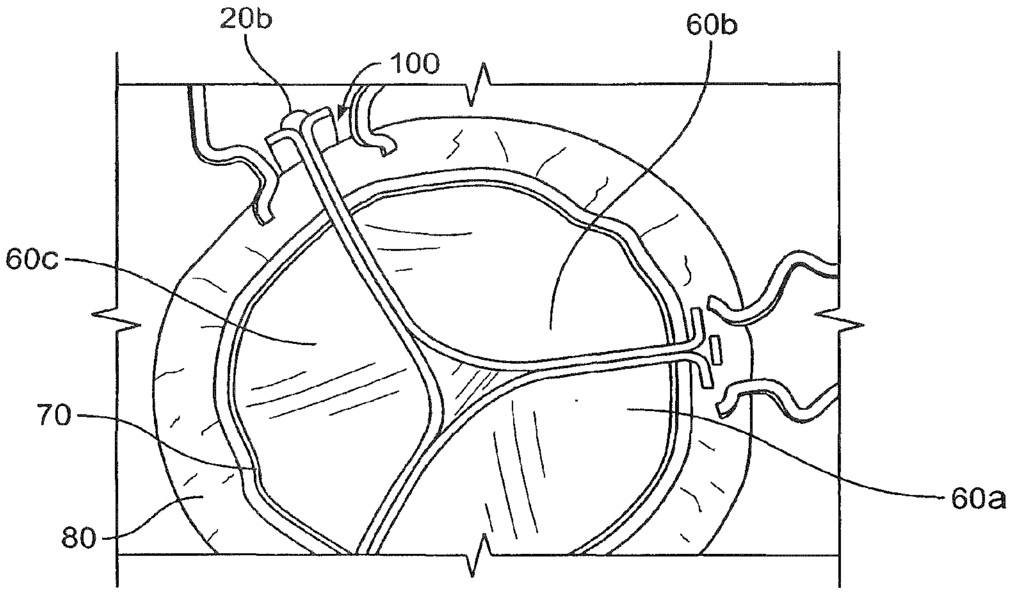

FIG. 13

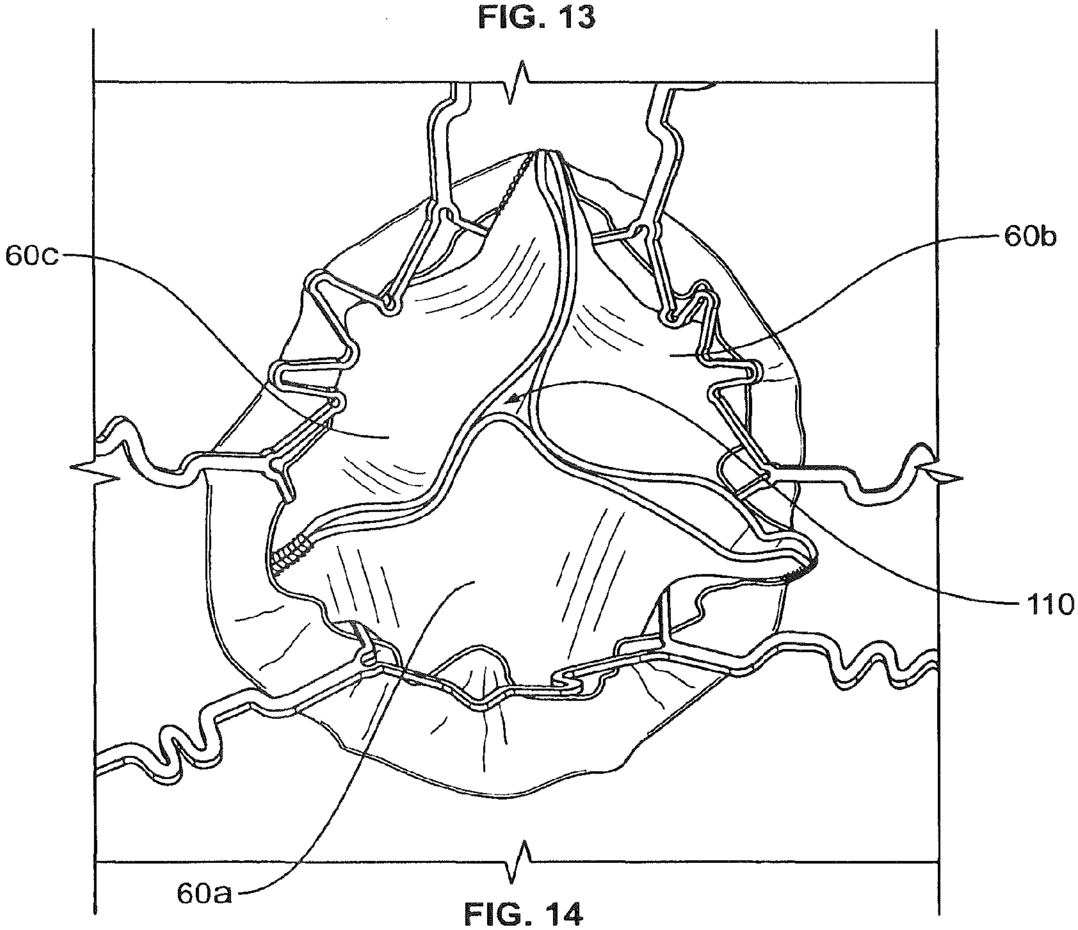

FIG. 14

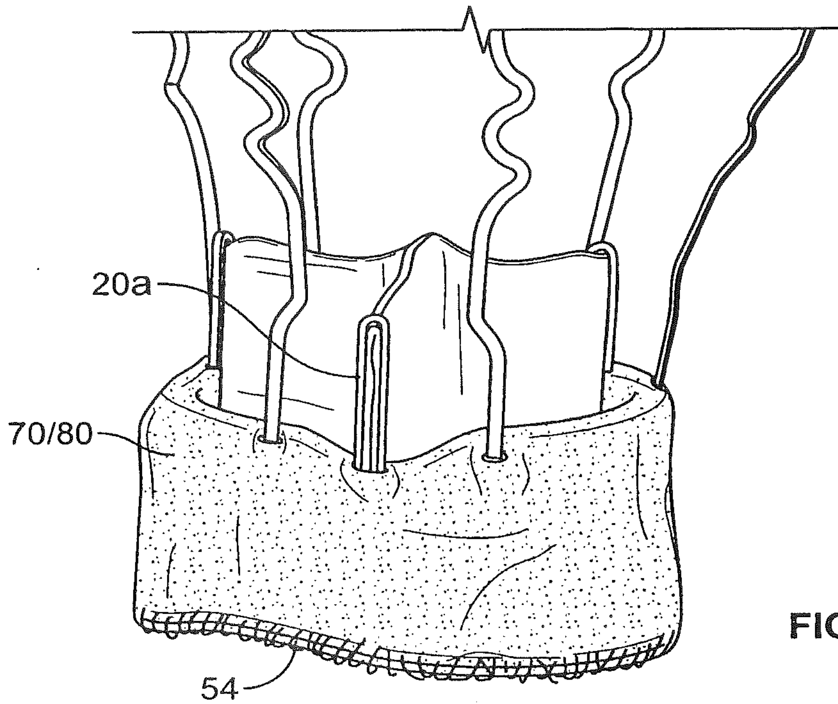

FIG. 15A

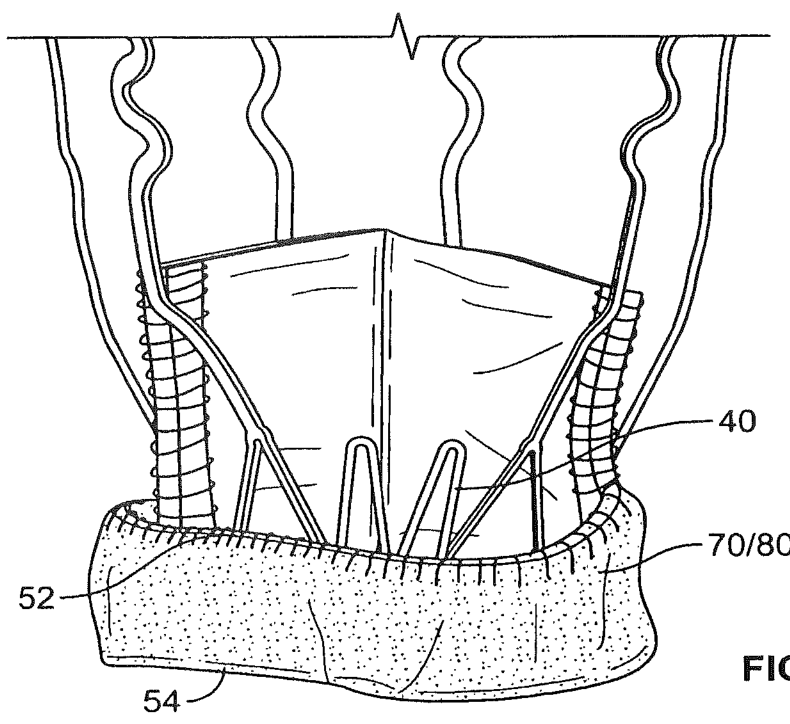

FIG. 15B

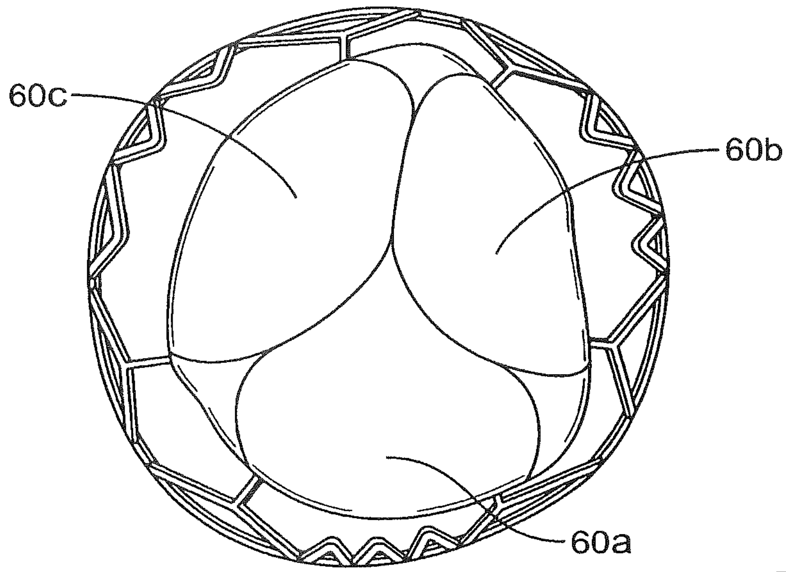

FIG. 16

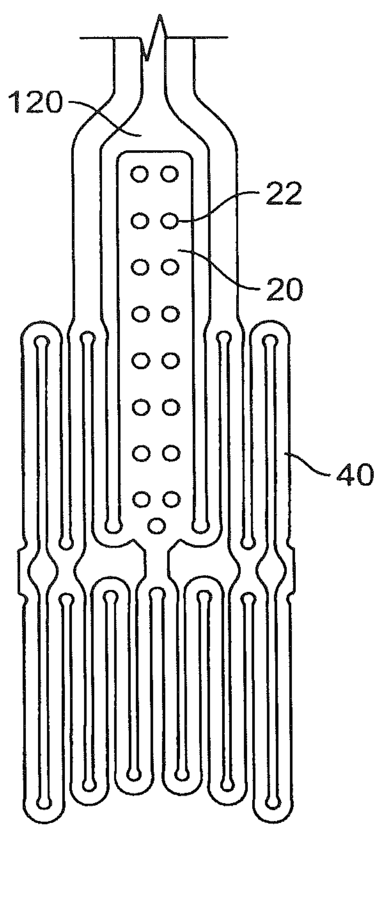

FIG. 17

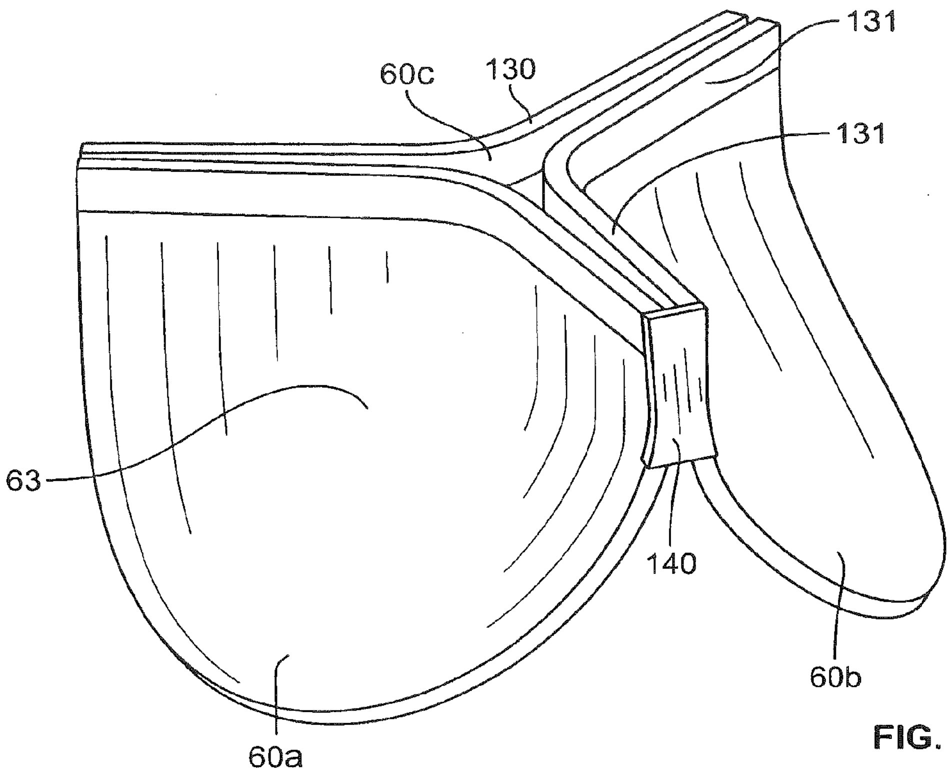

FIG. 18A

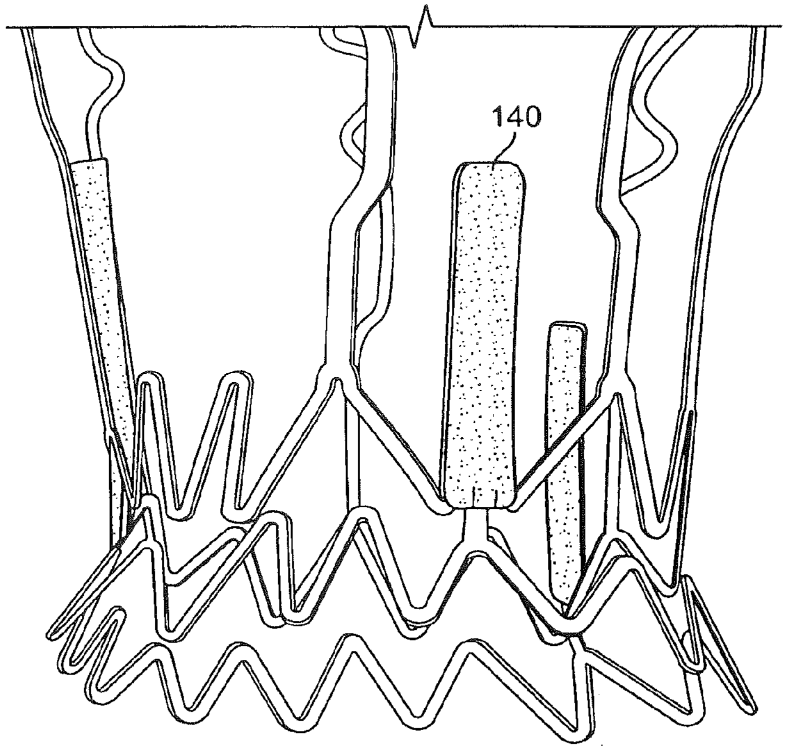

FIG. 18B

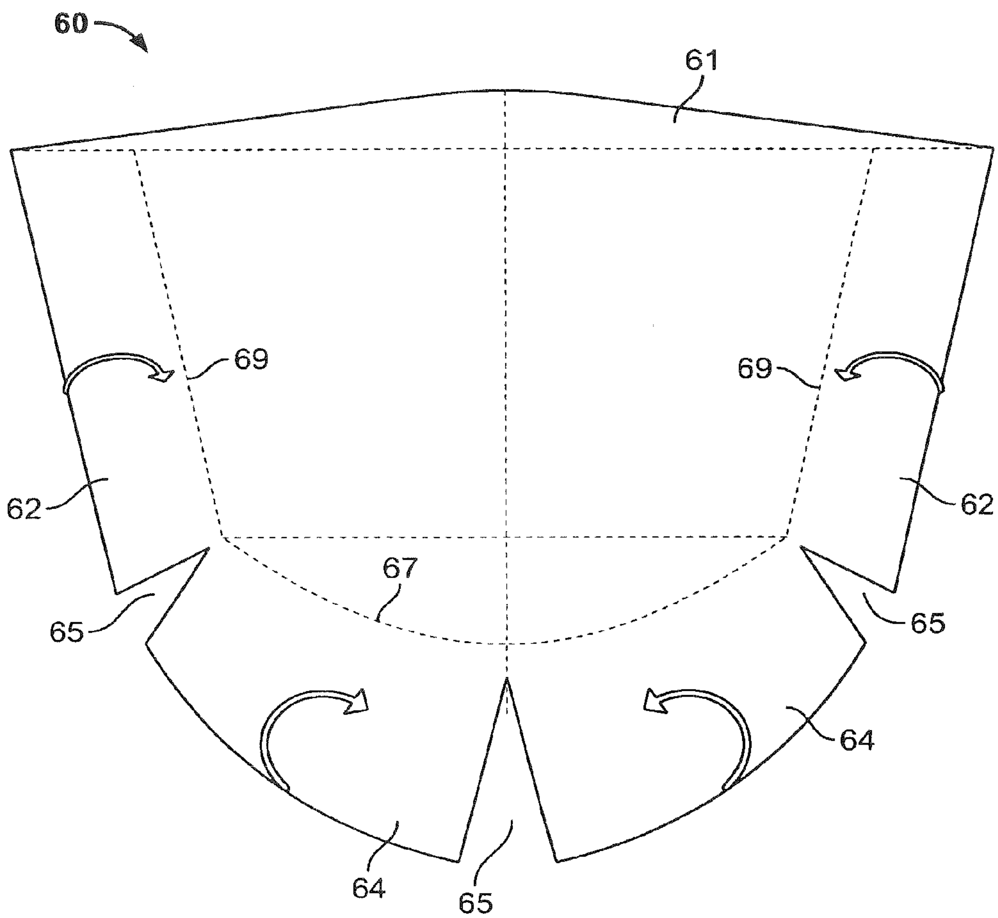

FIG. 19

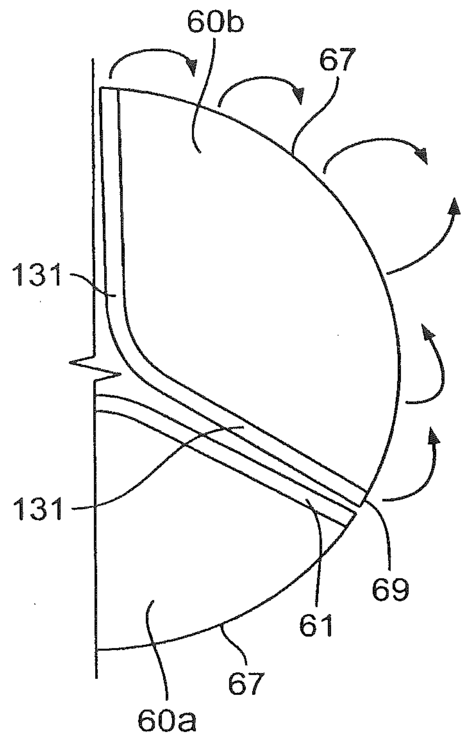

FIG. 20A

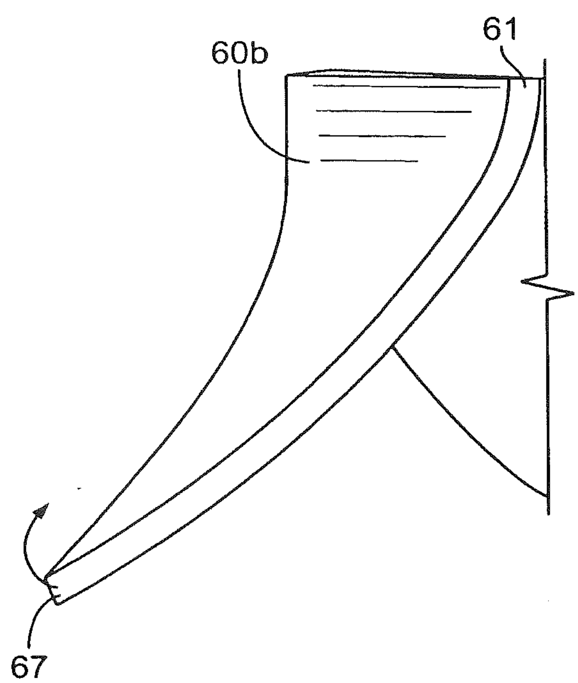

FIG. 20B

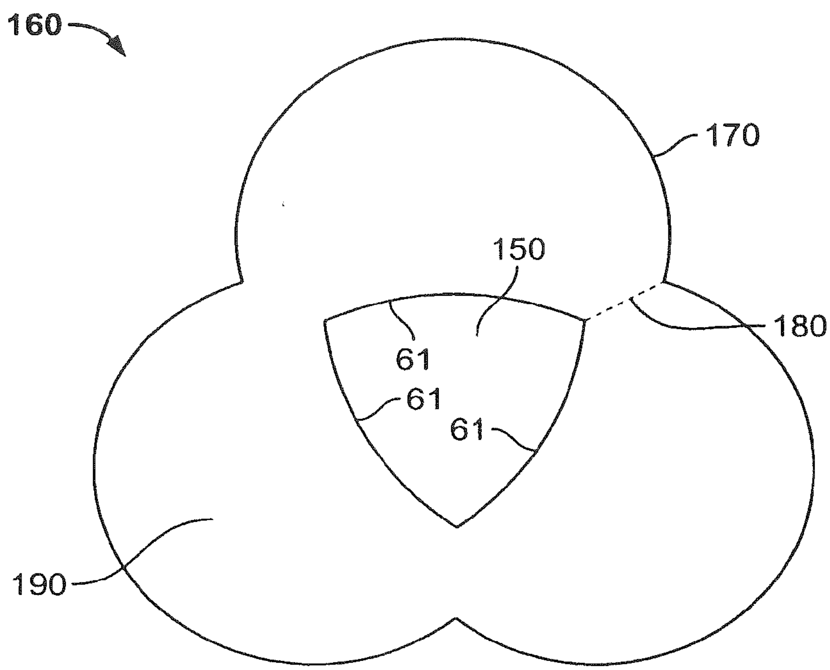

FIG. 21

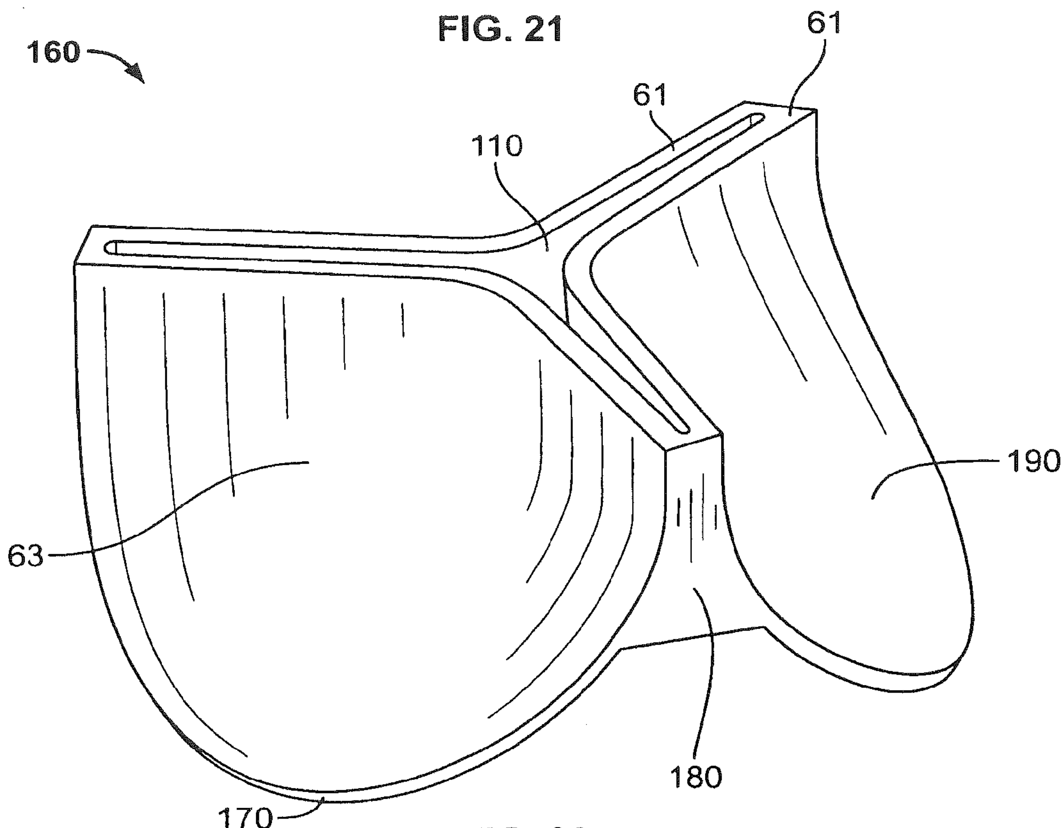

FIG. 22

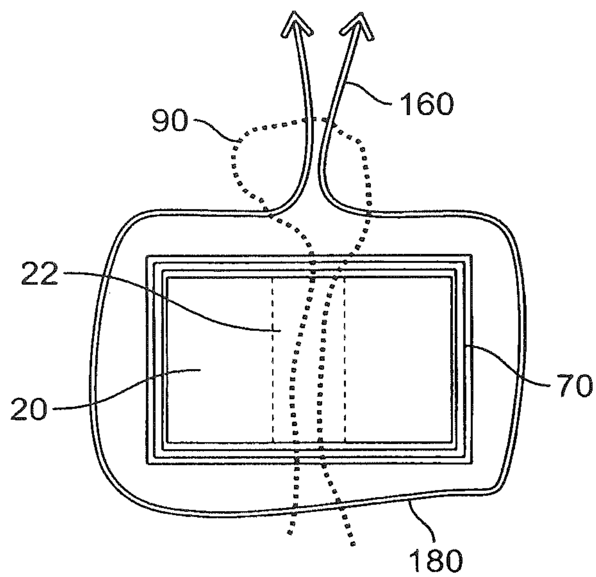

FIG. 23A

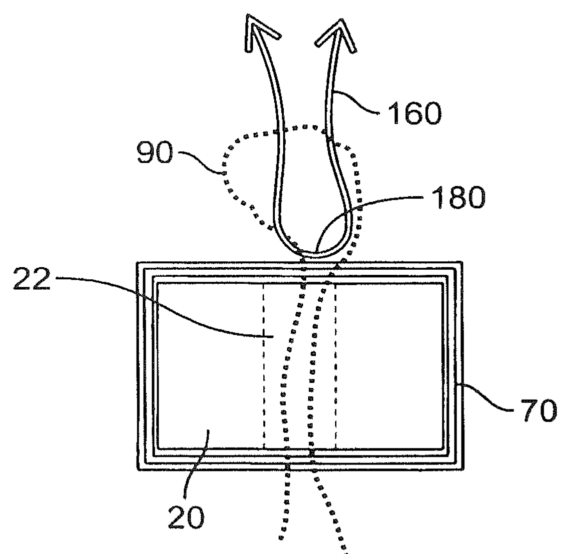

FIG. 23B

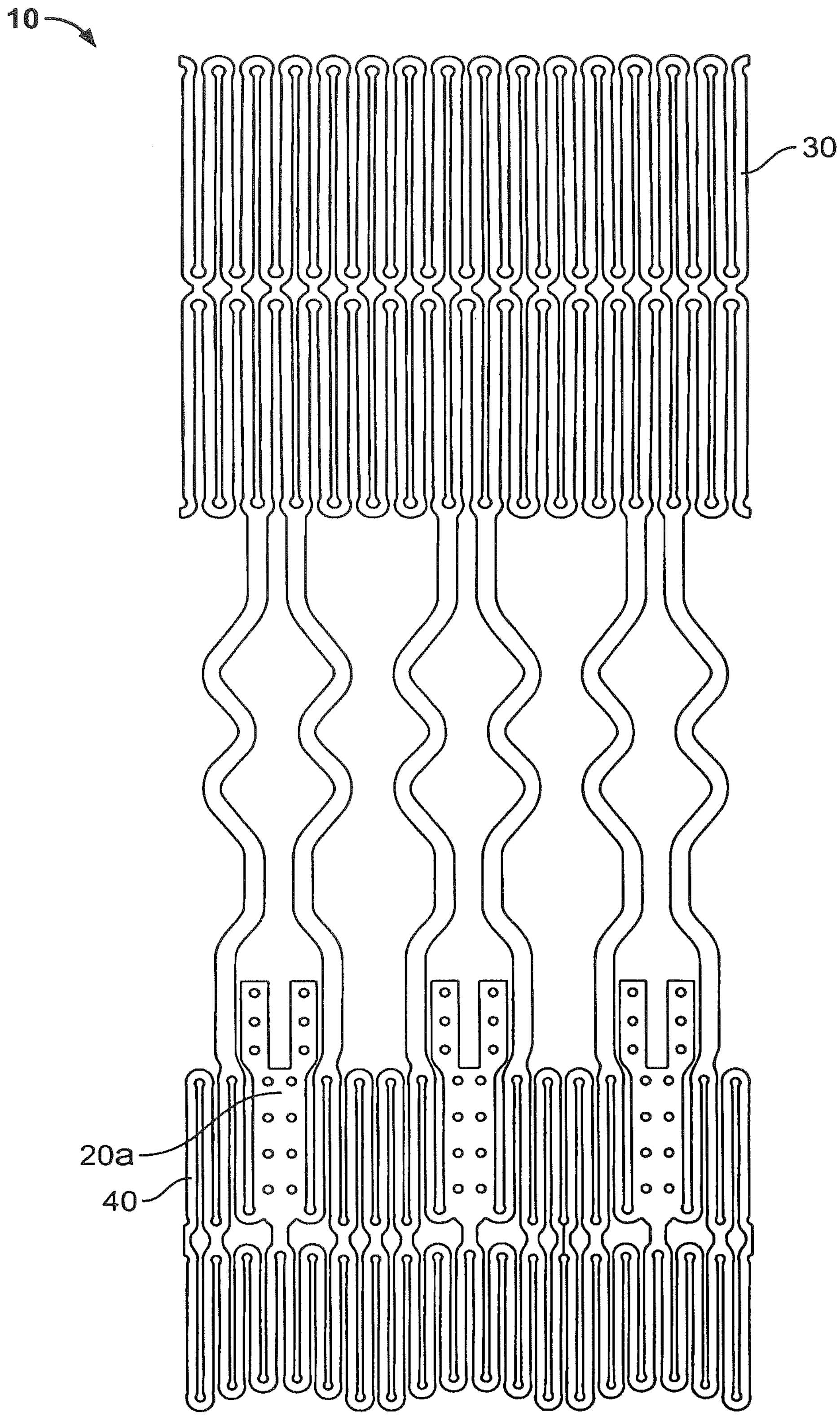

FIG. 24A

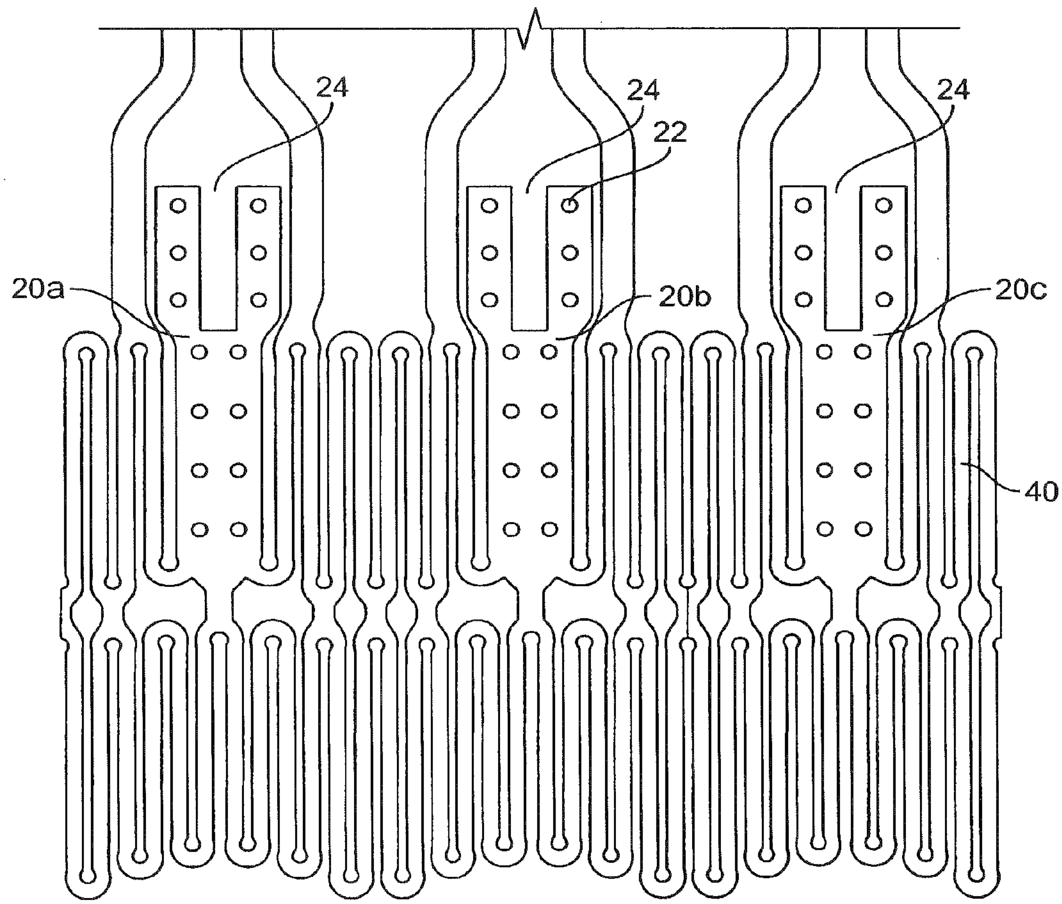

FIG. 24B

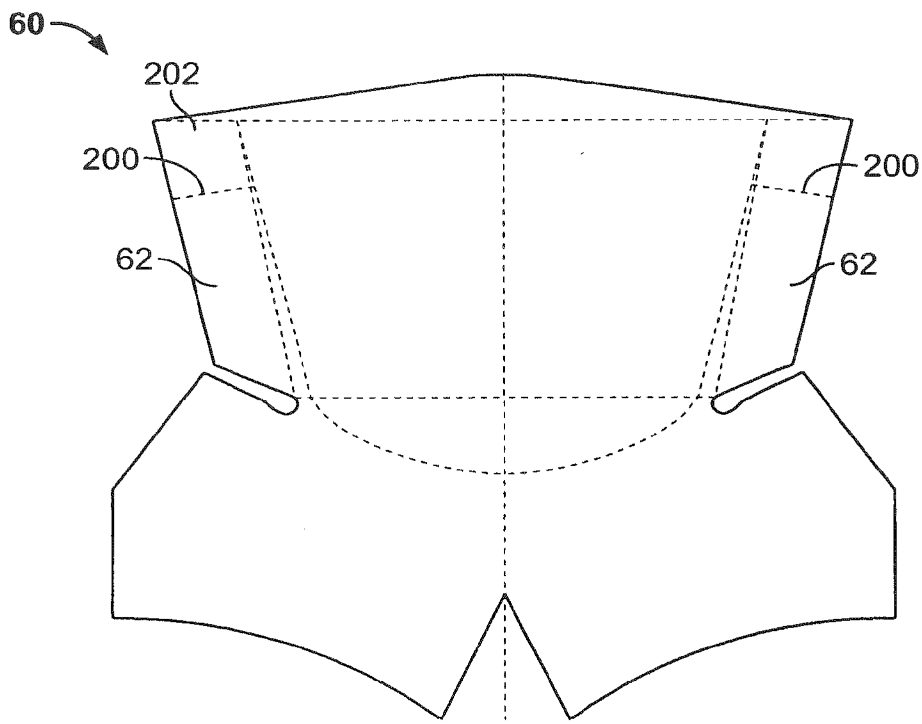

FIG. 25A

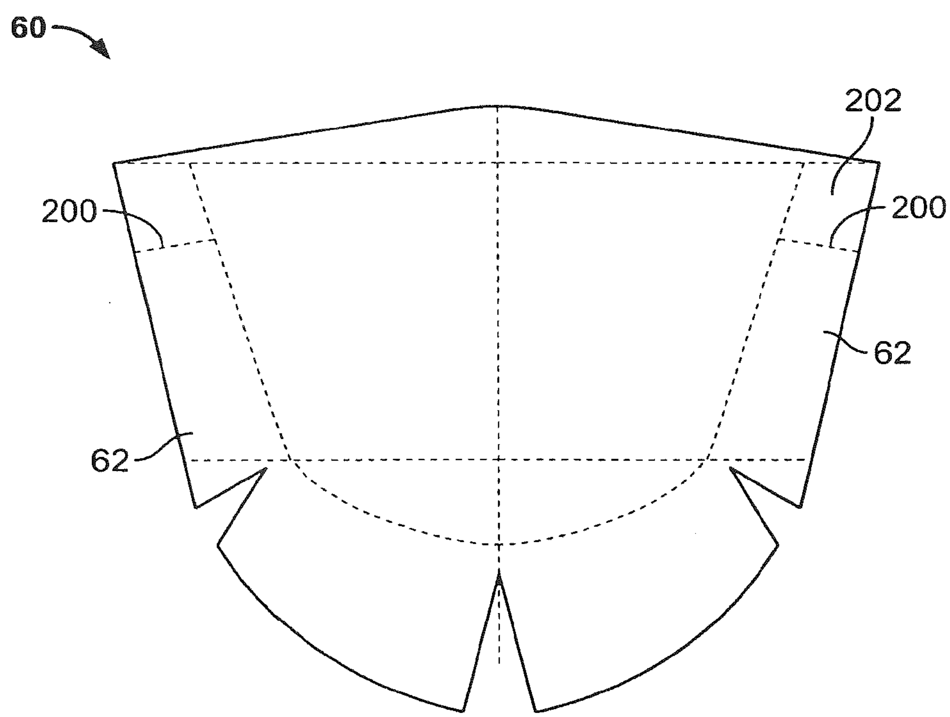

FIG. 25B

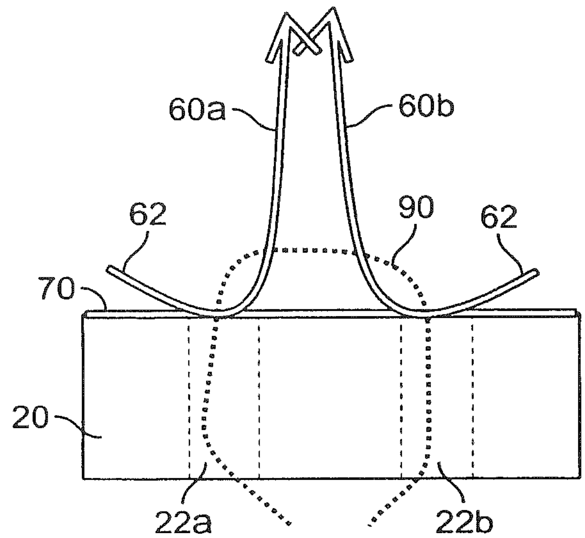

FIG. 26A

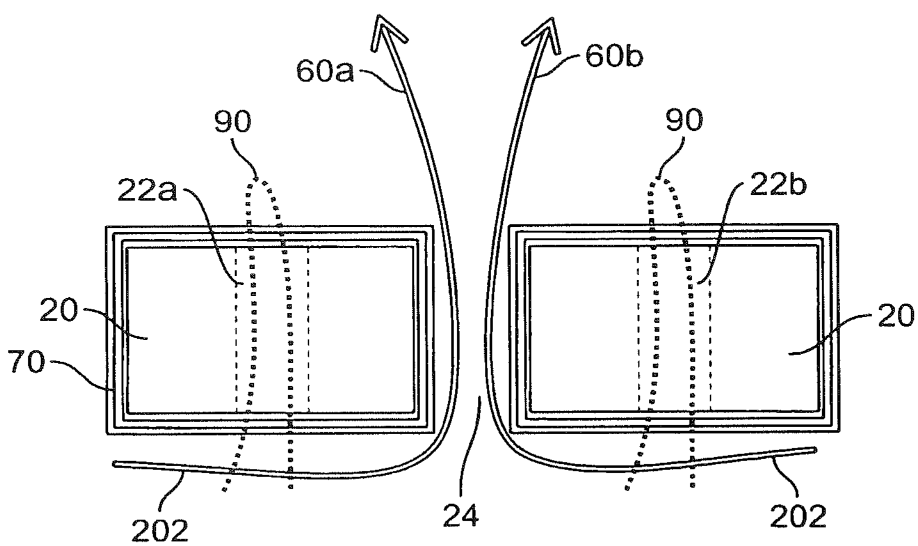

FIG. 26B

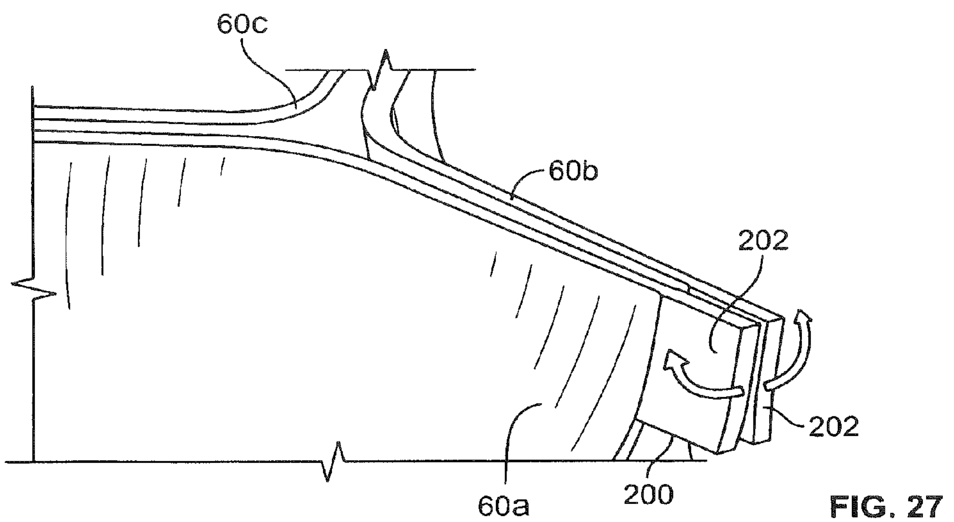

FIG. 27

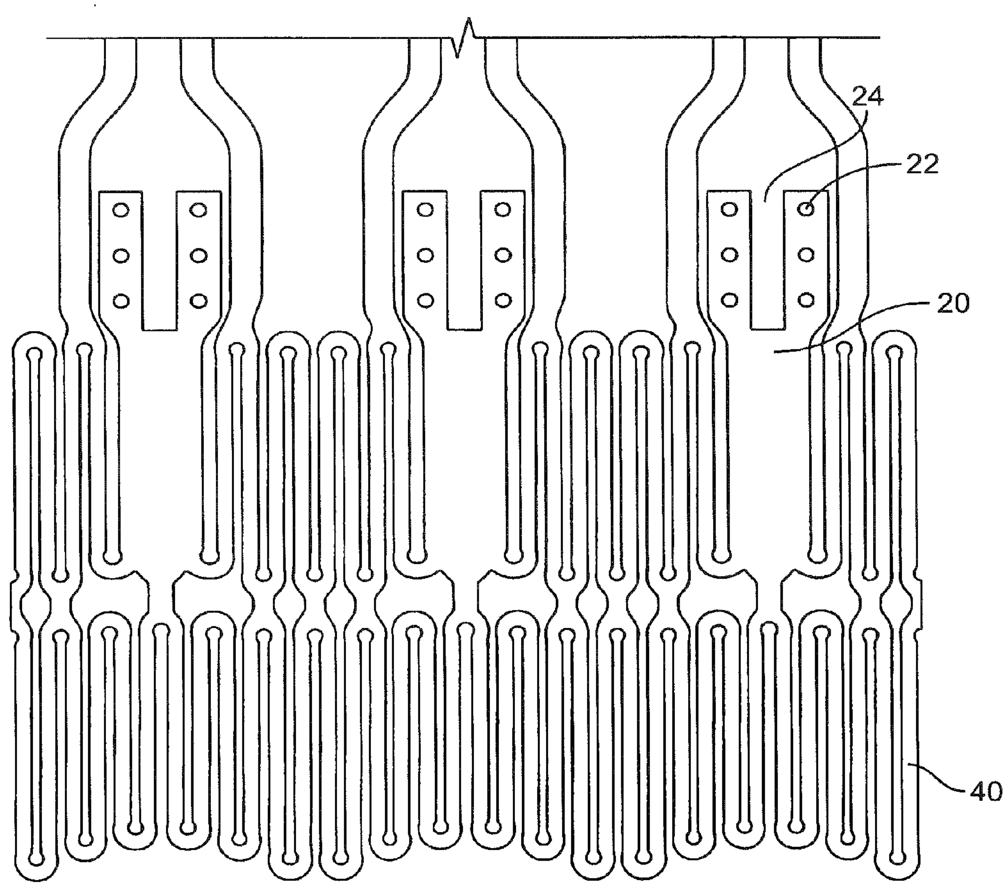

FIG. 28

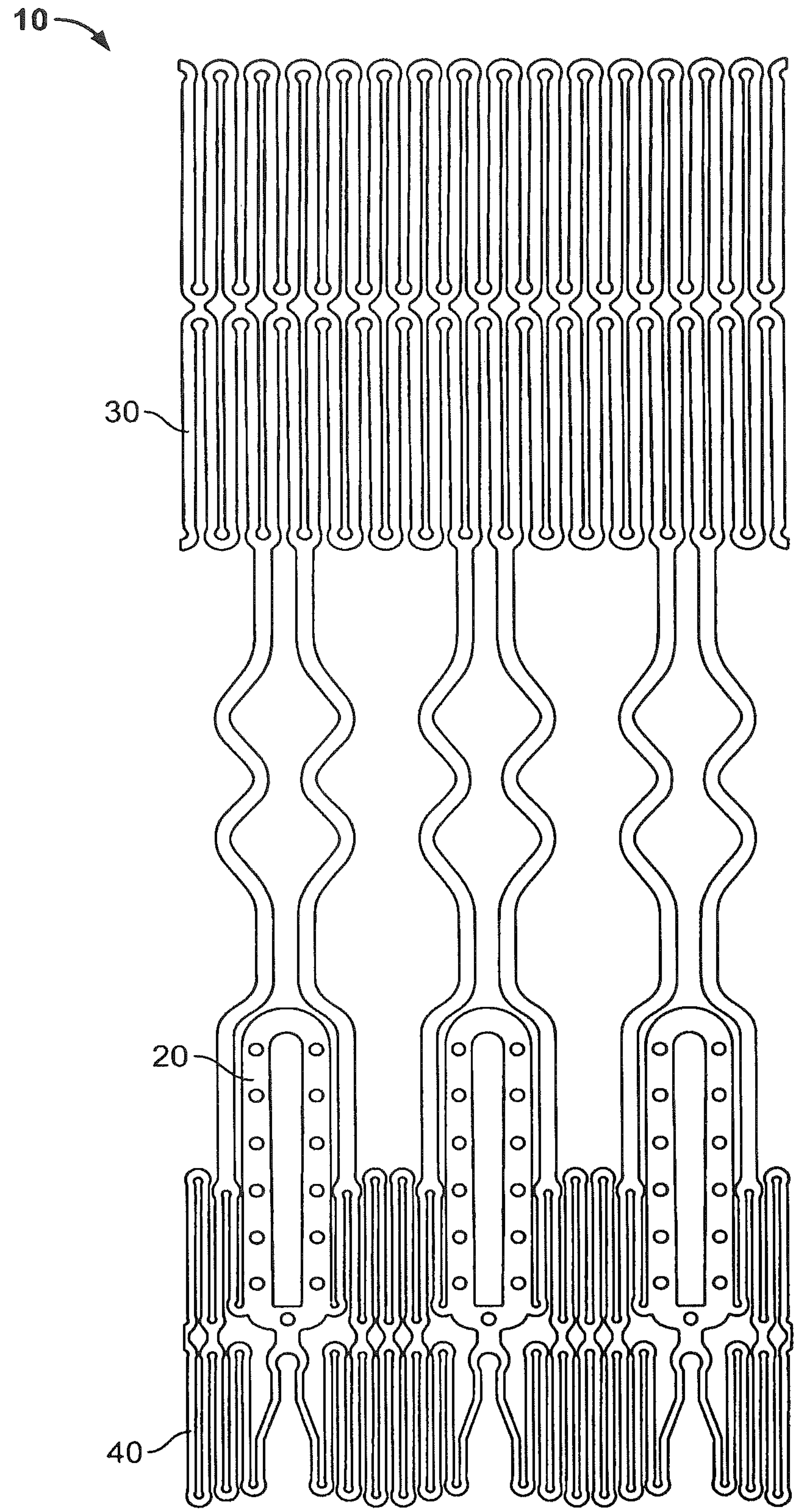

FIG. 29A

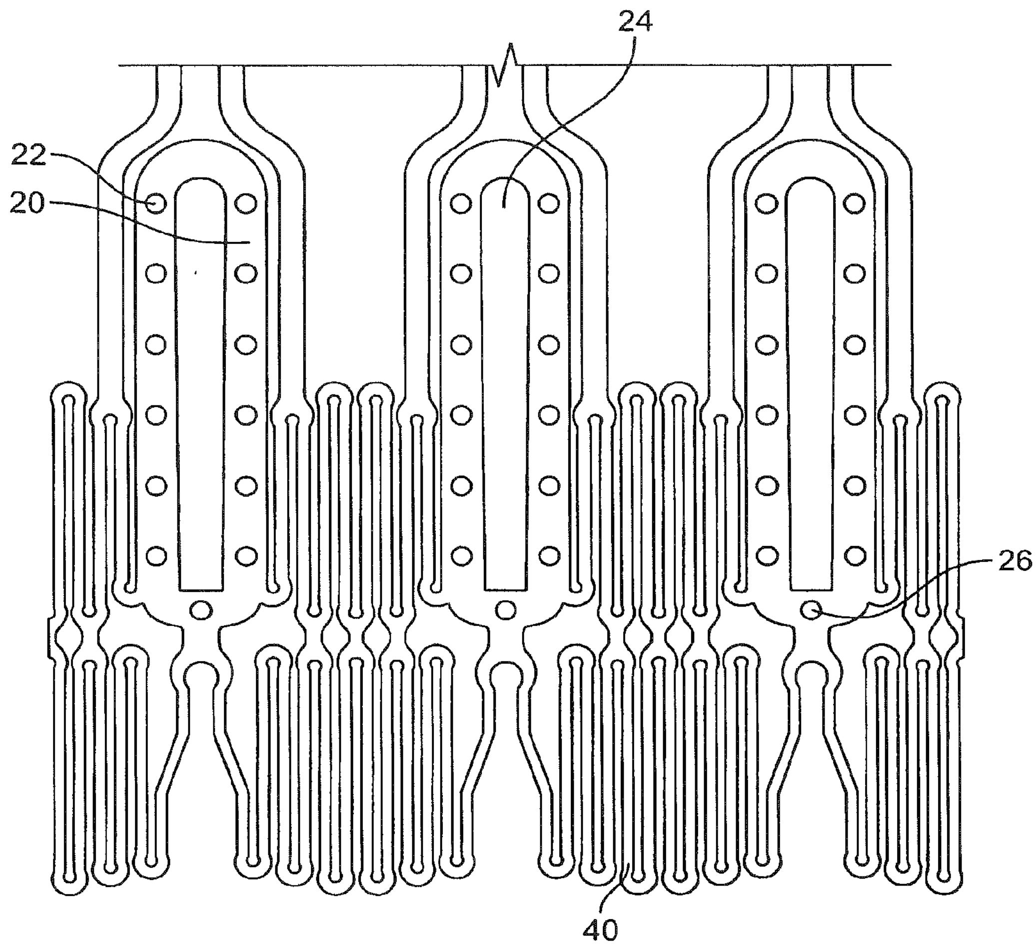

FIG. 29B

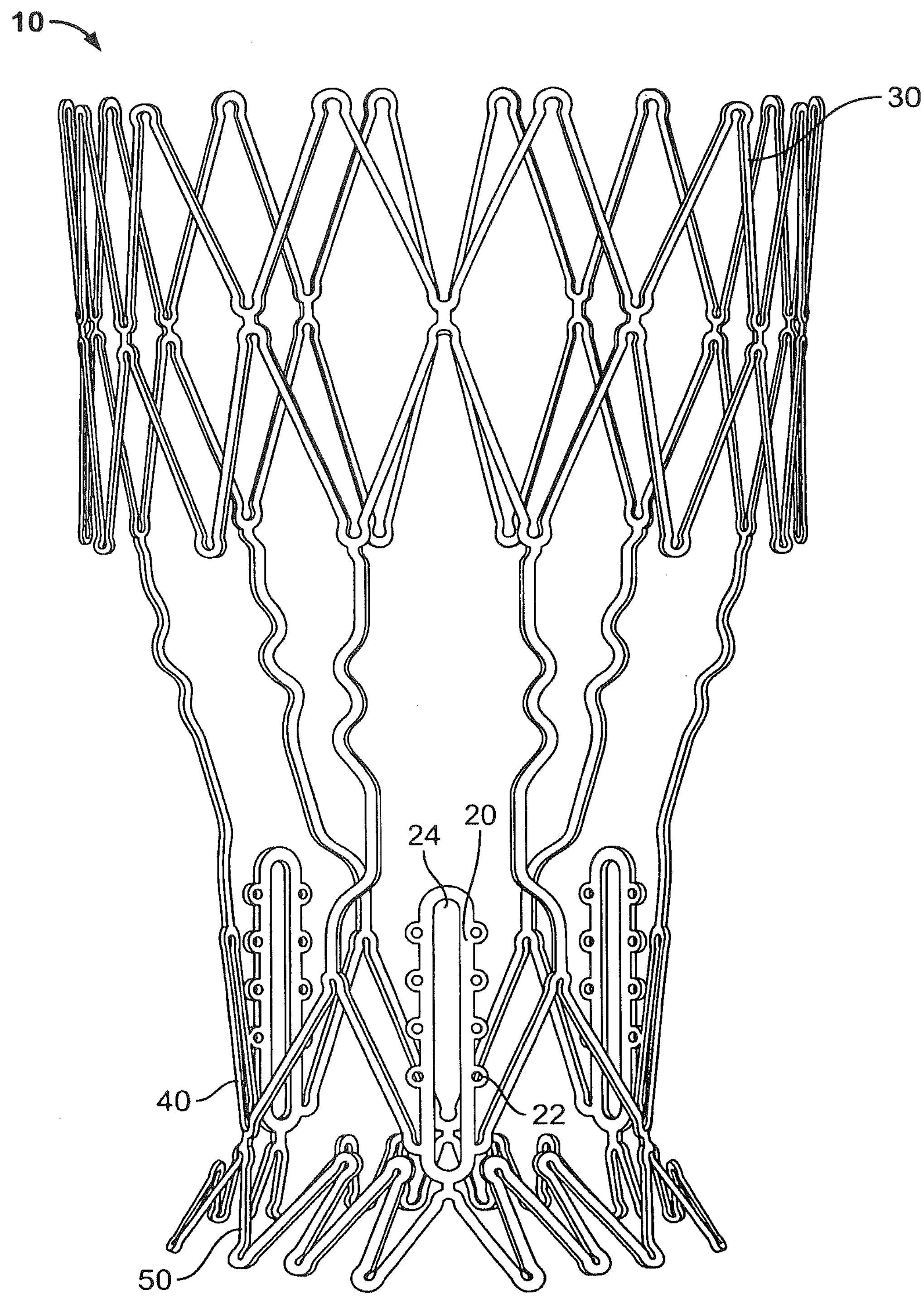

FIG. 30

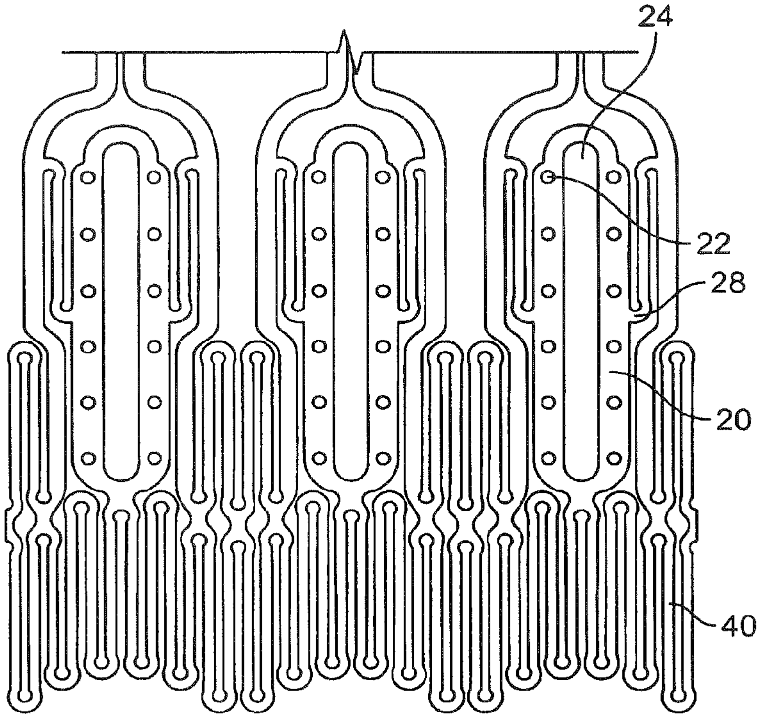

FIG. 31

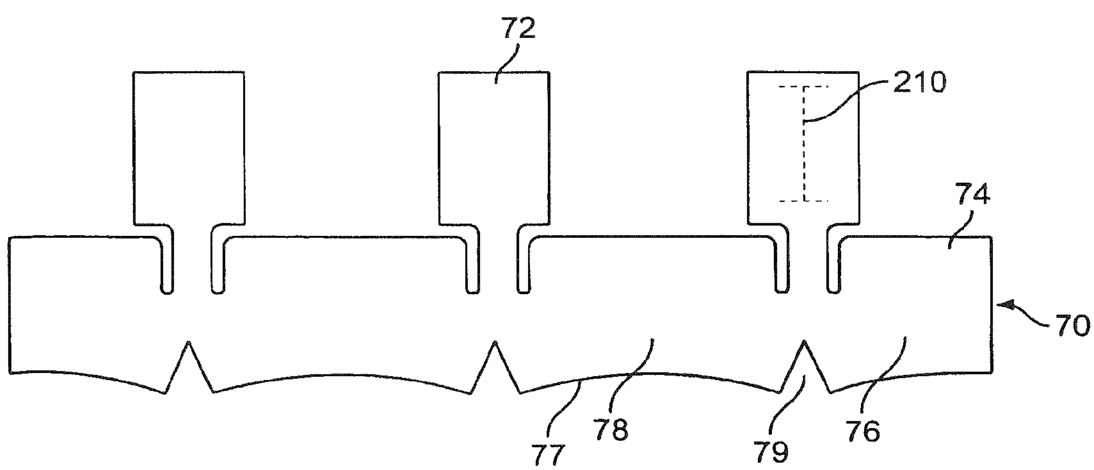

FIG. 32

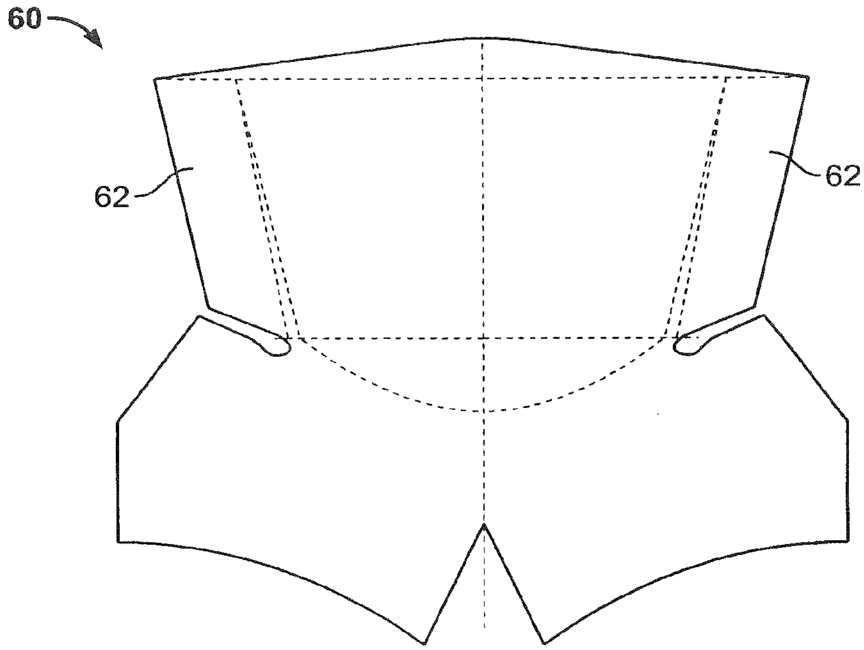

FIG. 33A

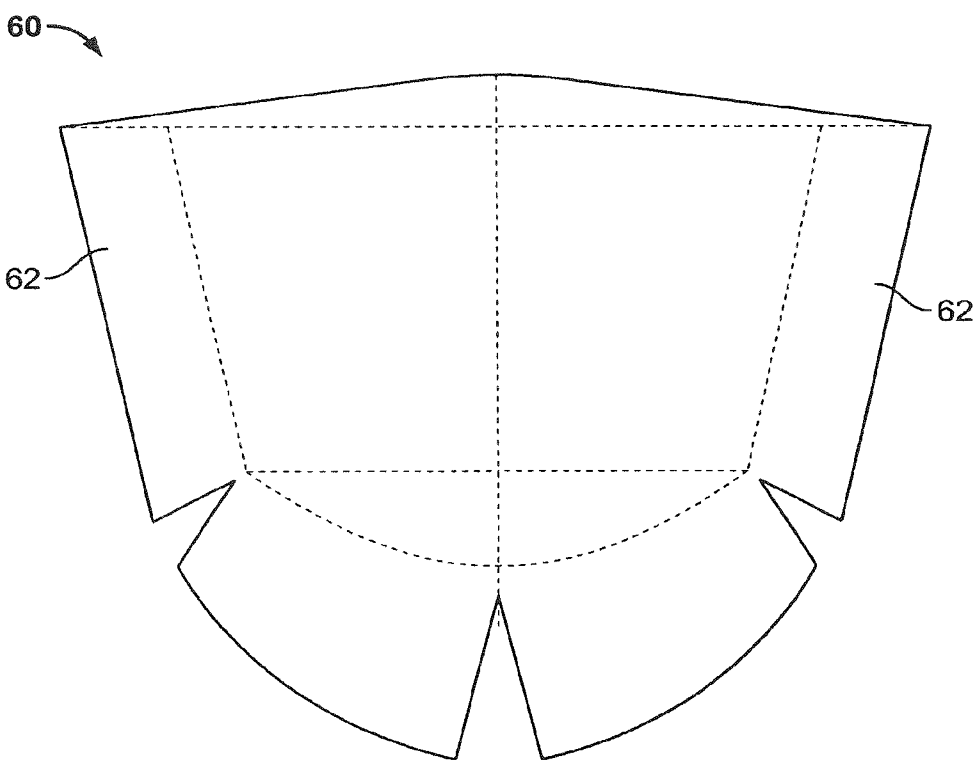

FIG. 33B

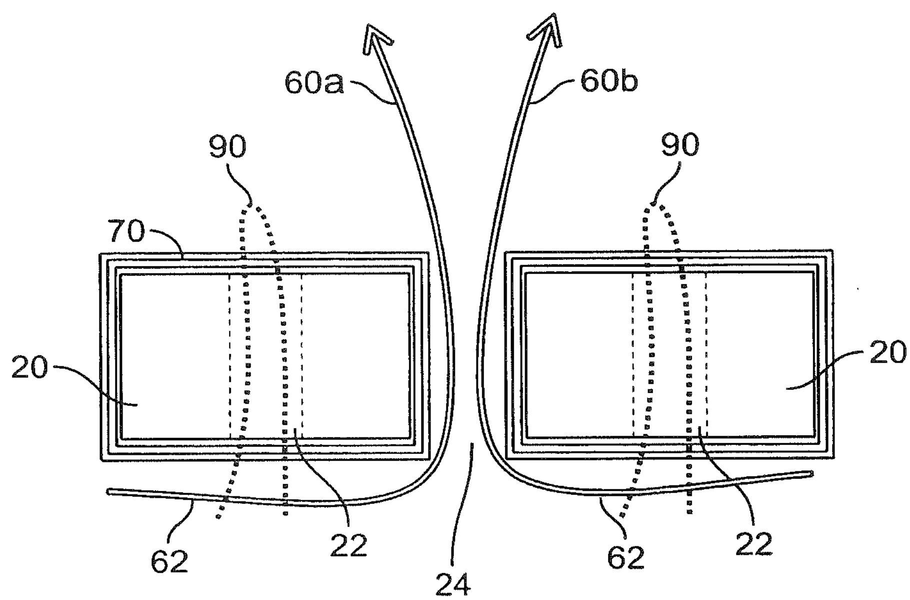

FIG. 34

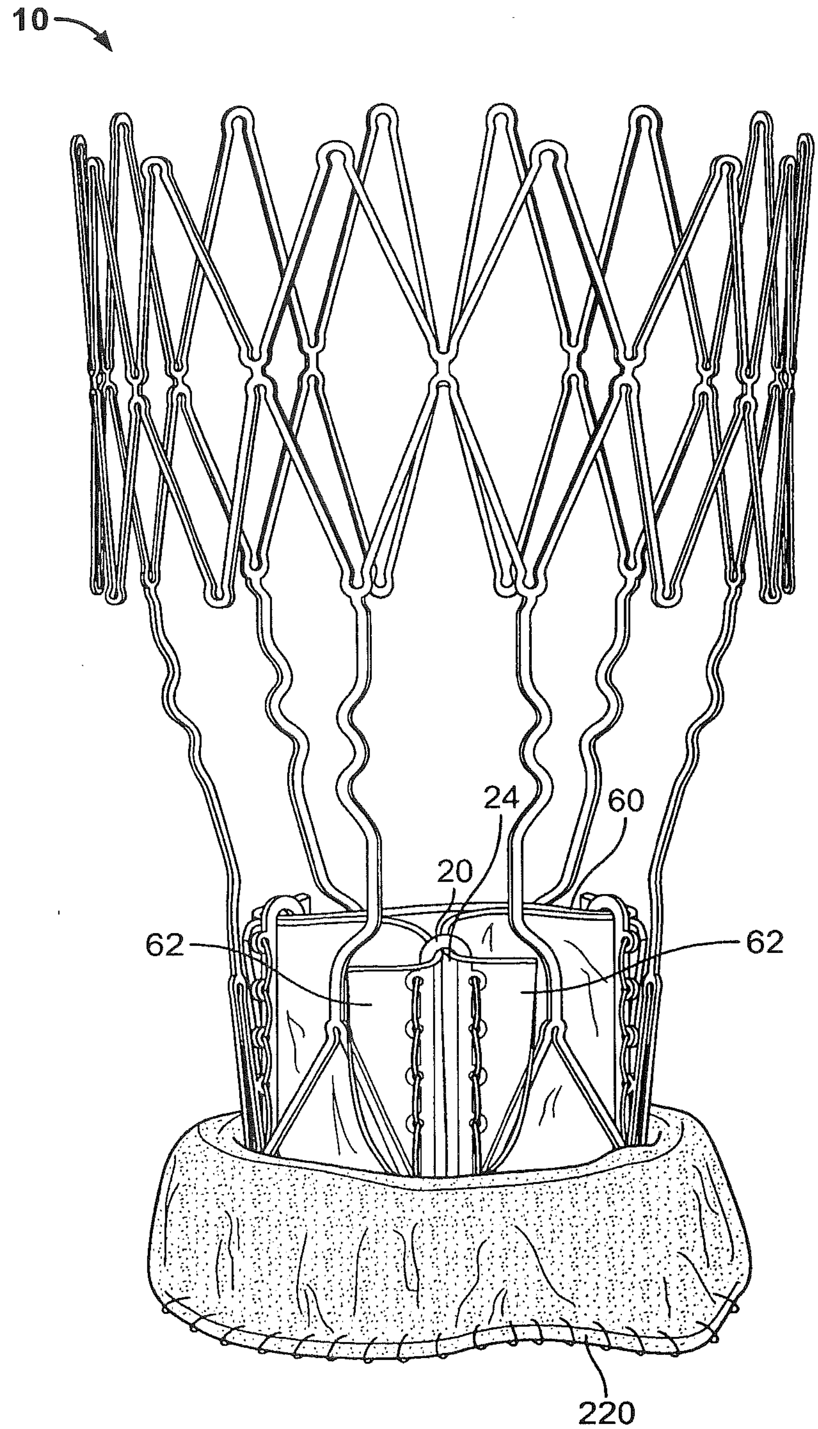

FIG. 35A

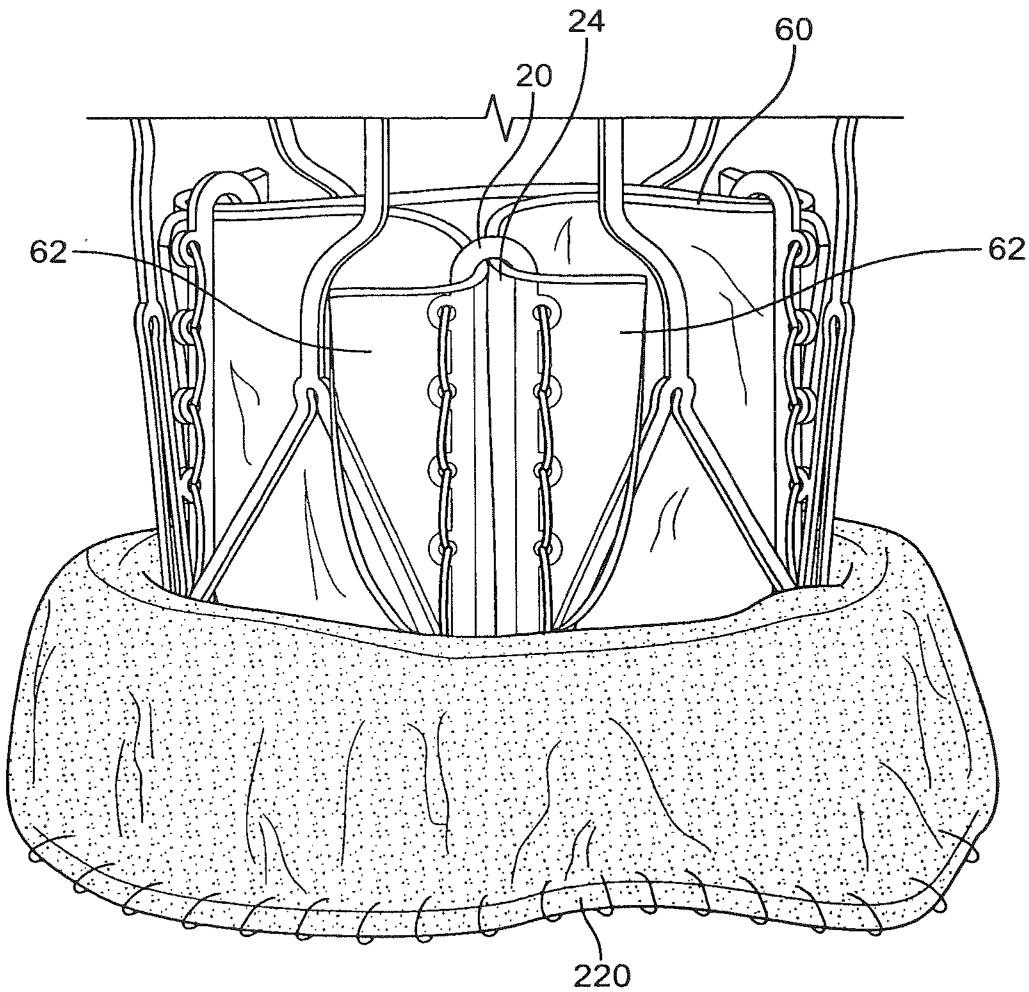

FIG. 35B

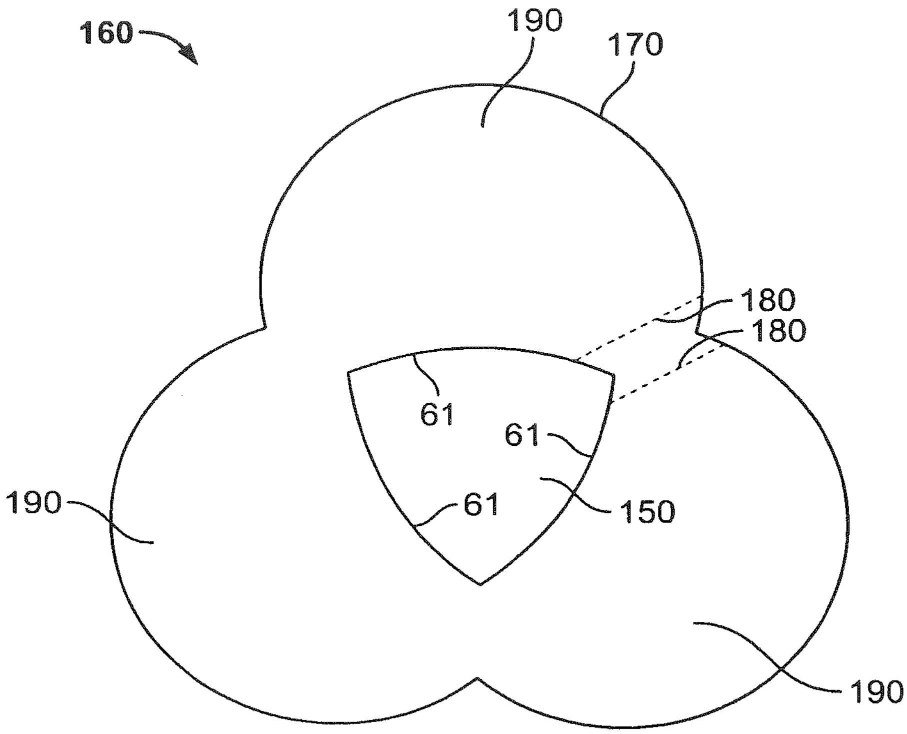
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FIG. 36

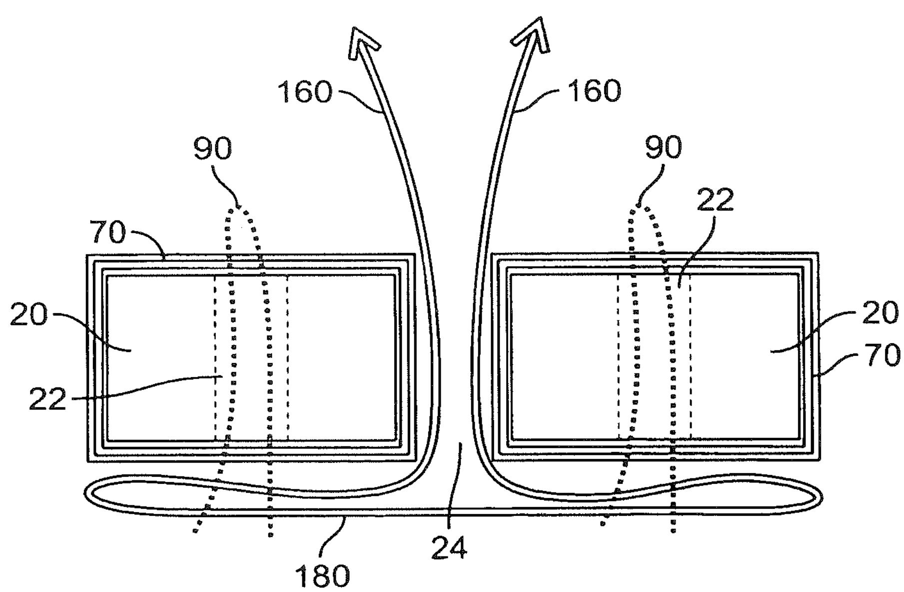
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FIG. 37

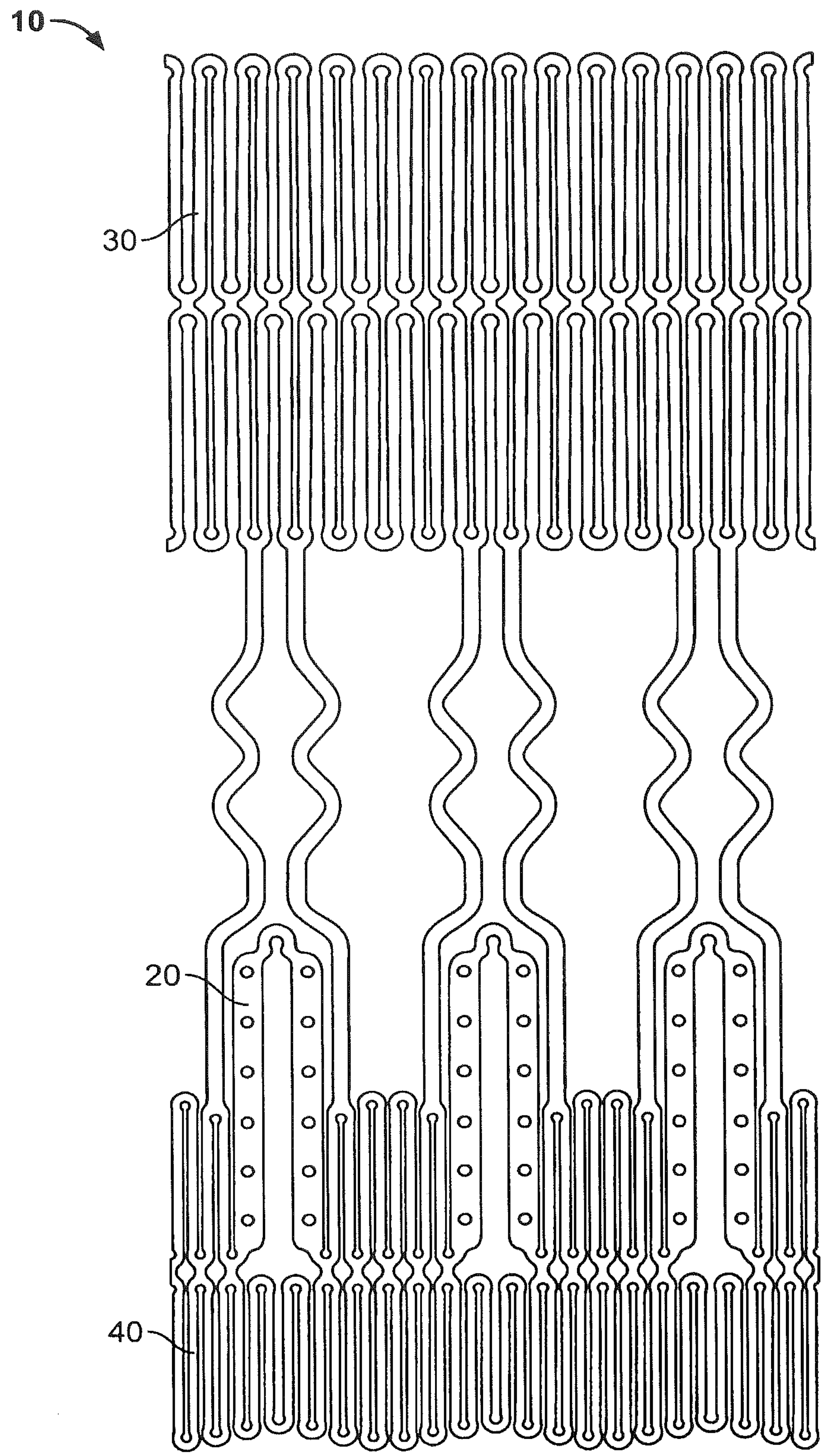

FIG. 38A

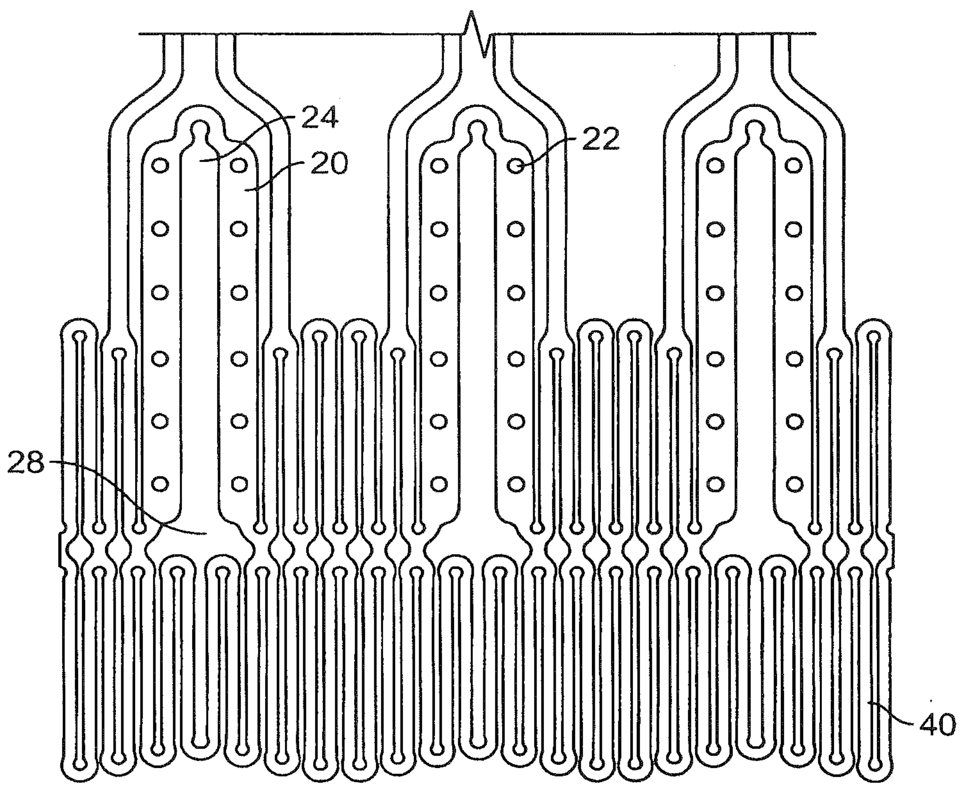

FIG. 38B

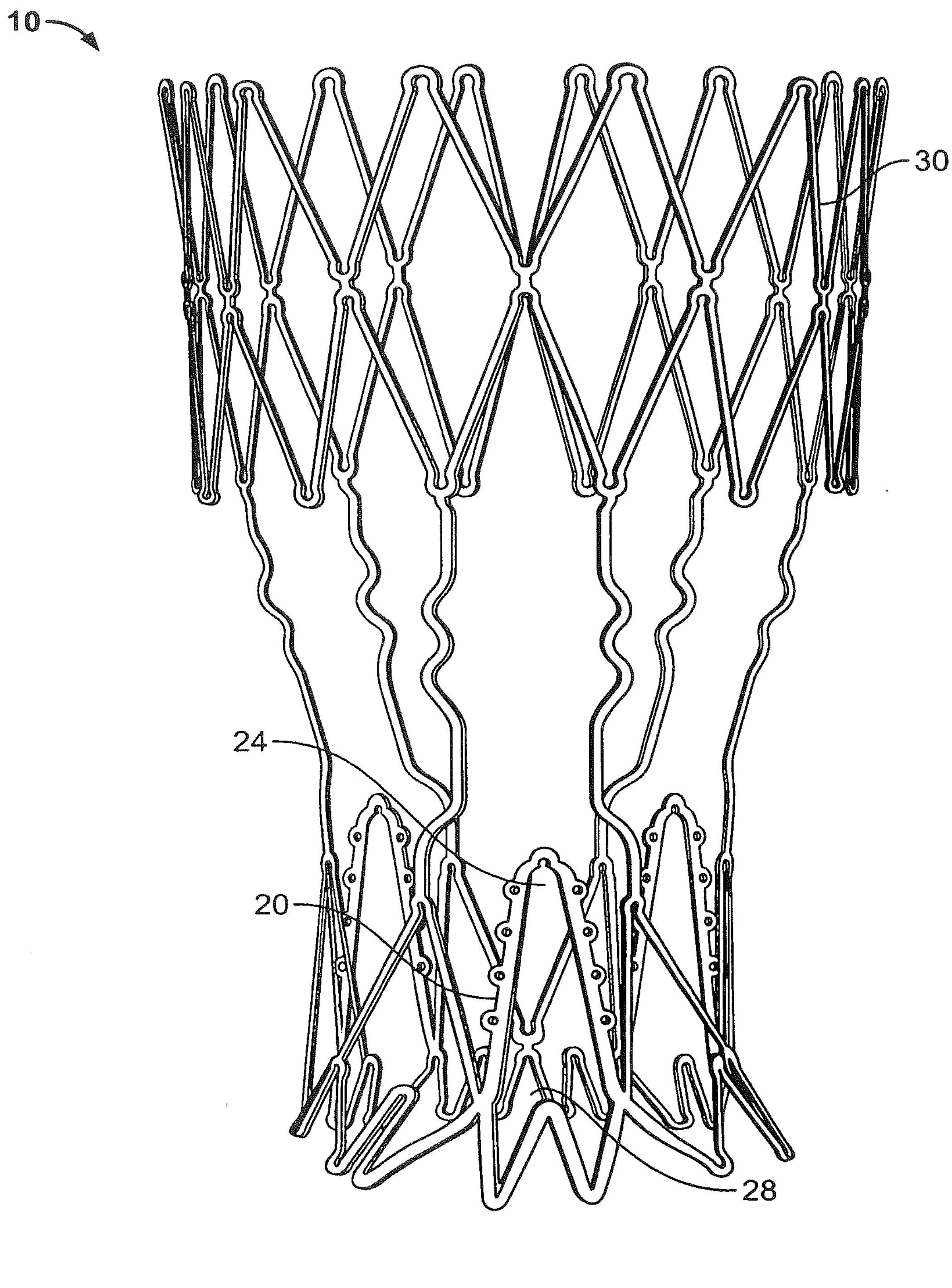

FIG. 39

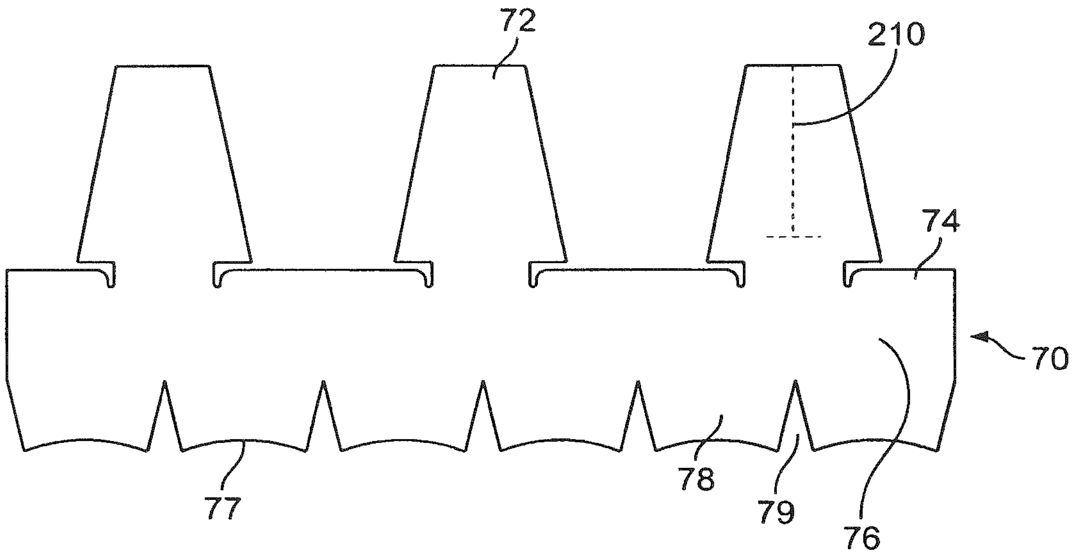

FIG. 40

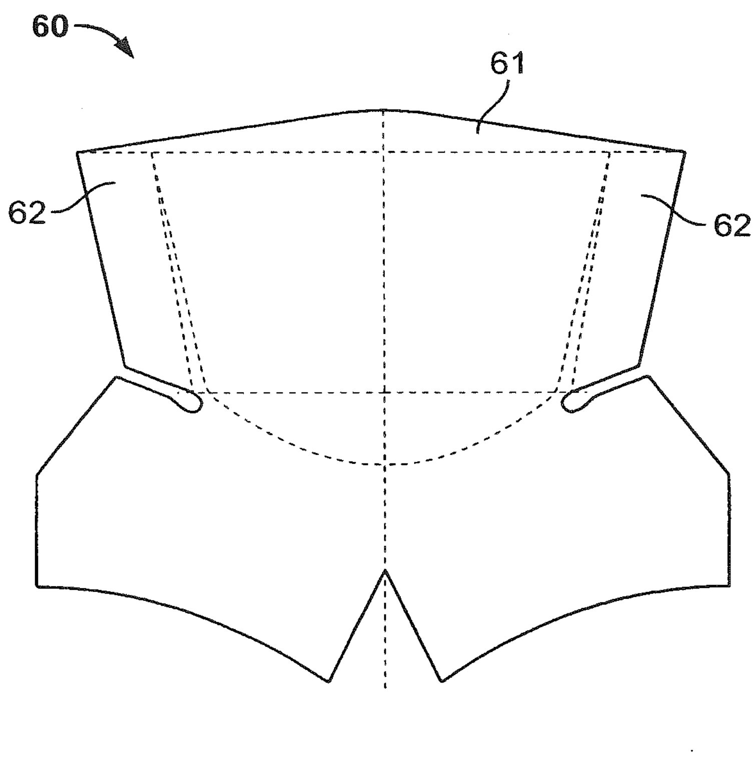

FIG. 41A

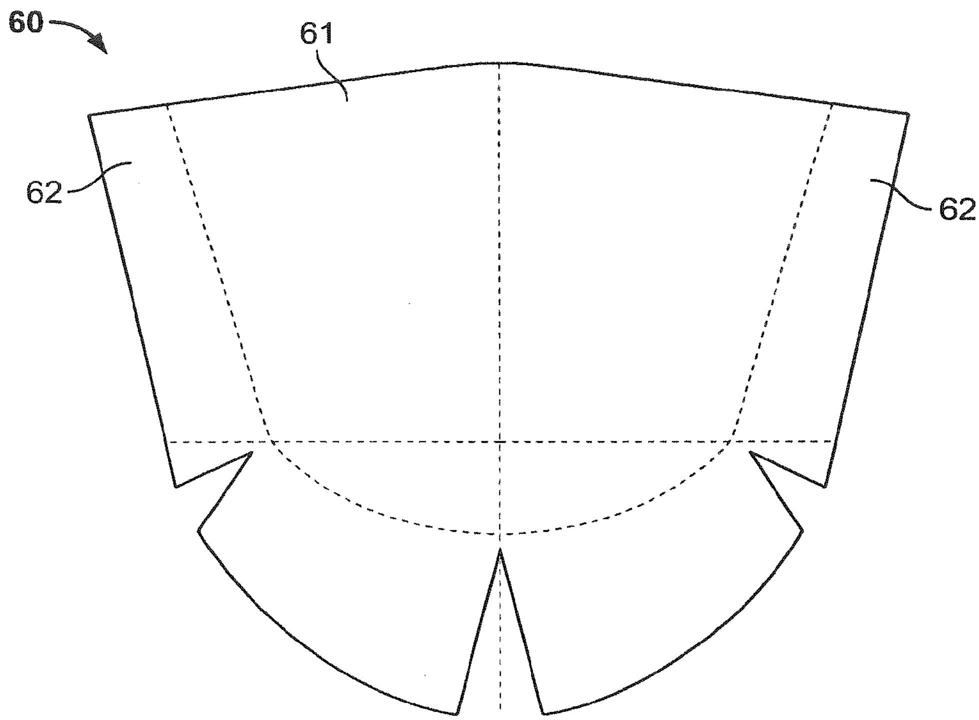

FIG. 41B

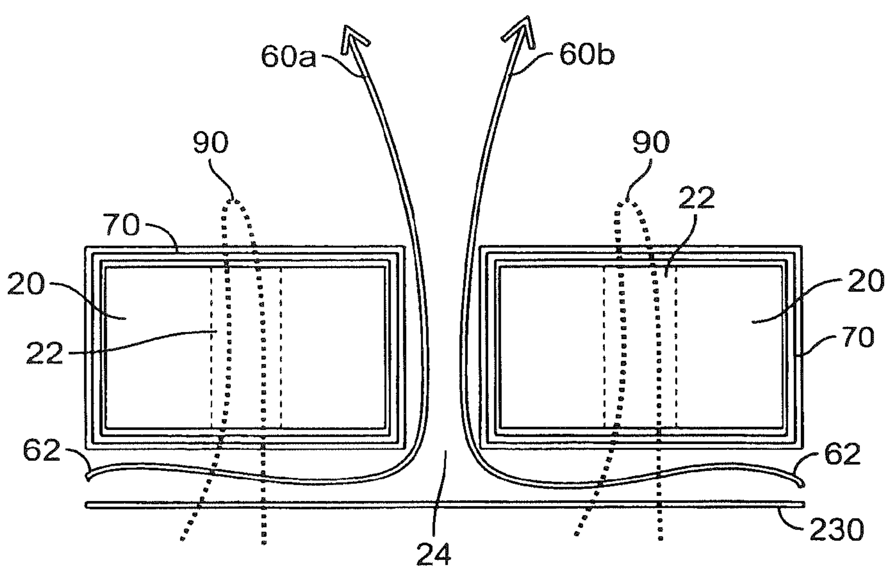

FIG. 42

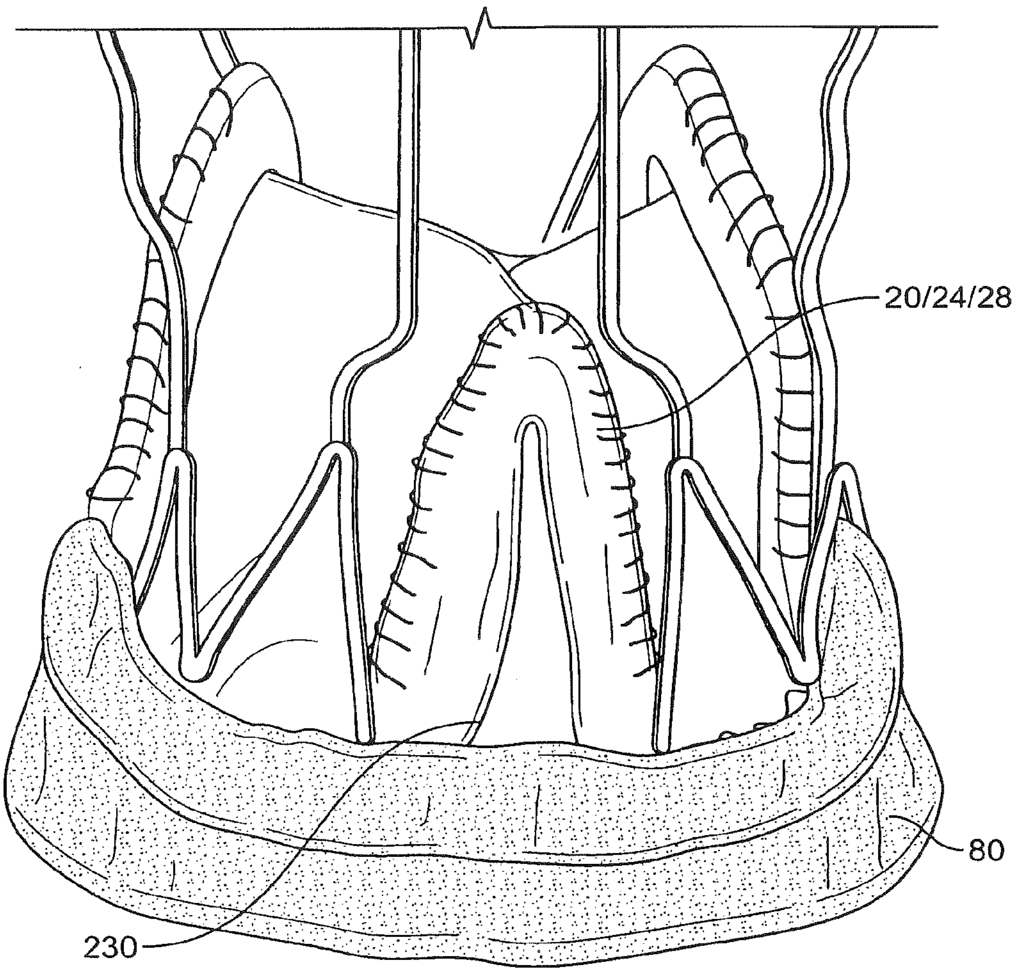

FIG. 43

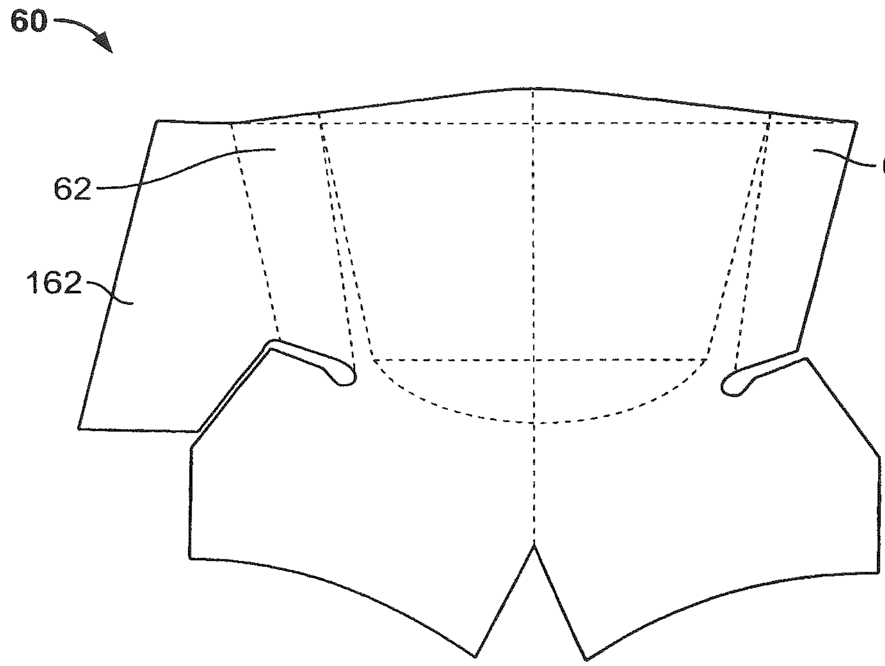

FIG. 44

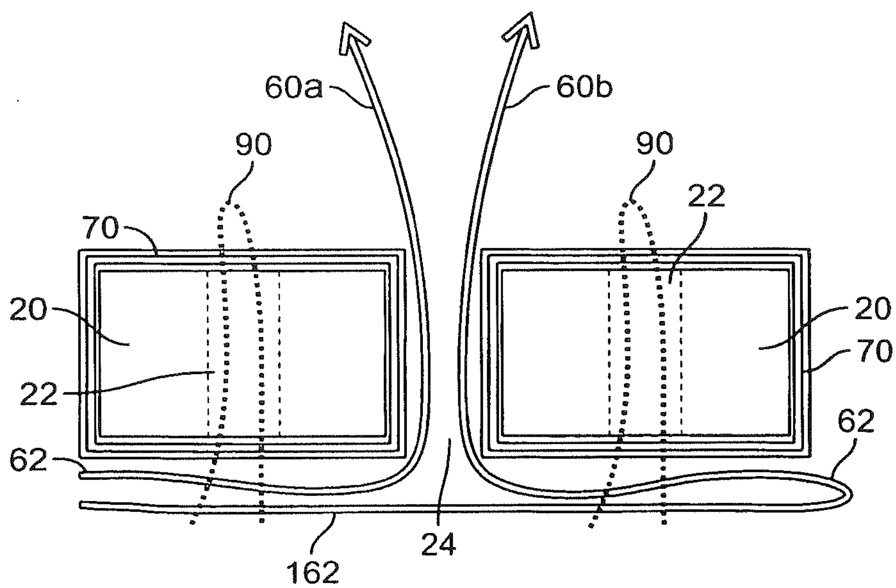

FIG. 45

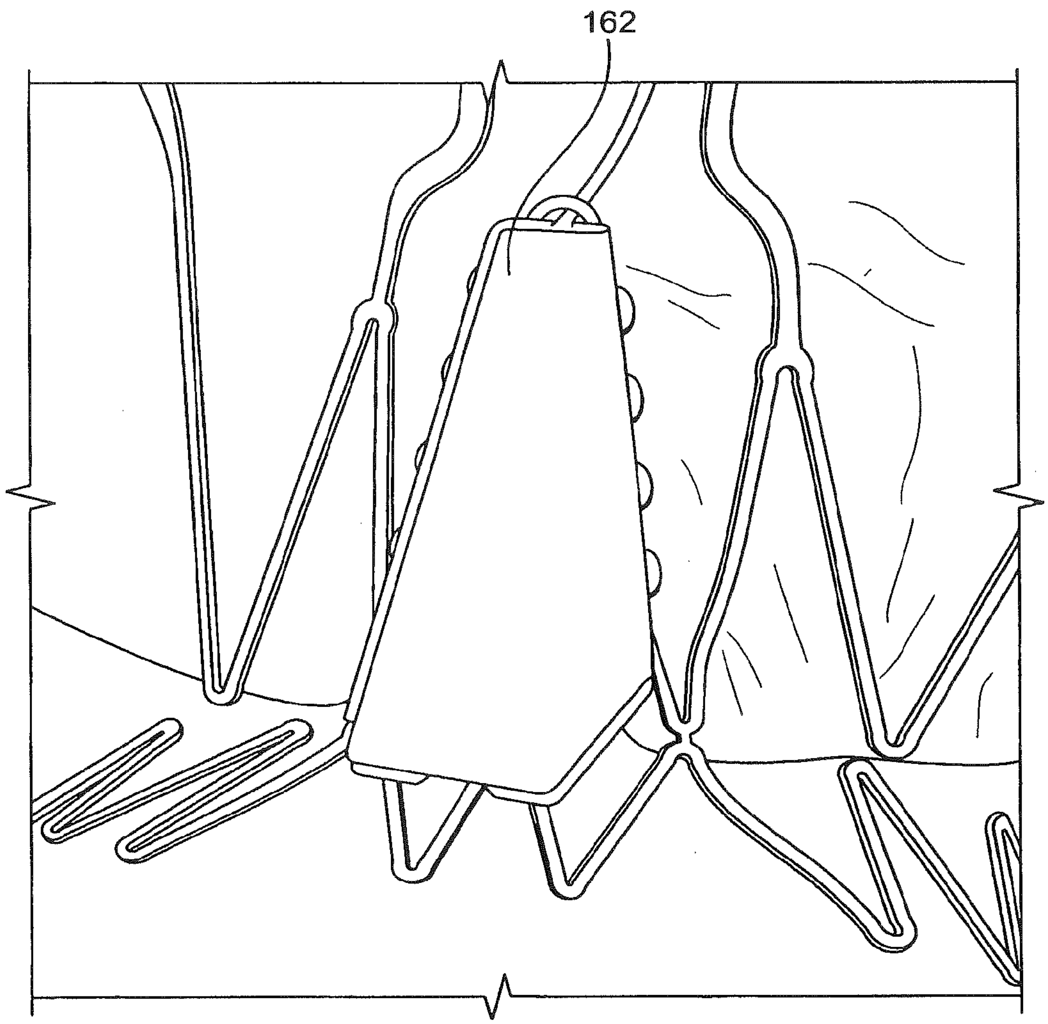

FIG. 46

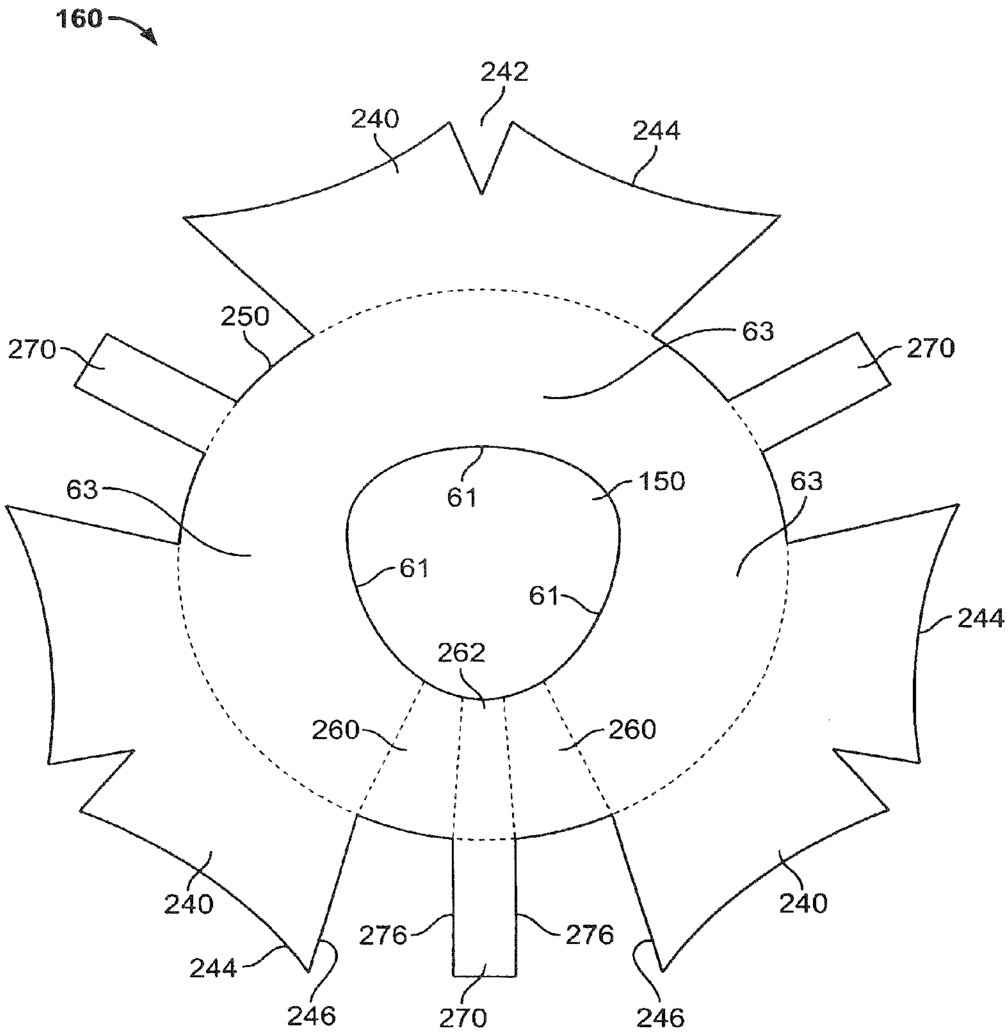
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FIG. 47

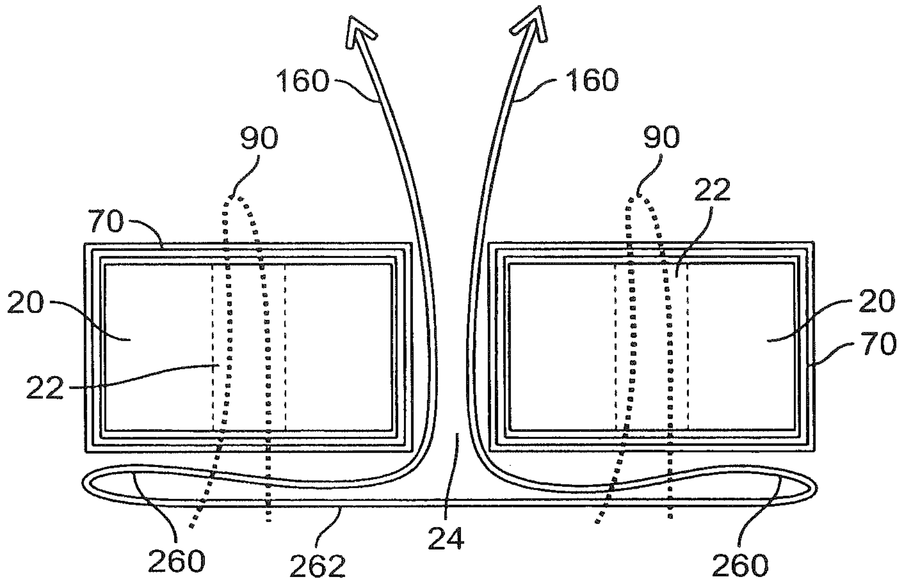


FIG. 48

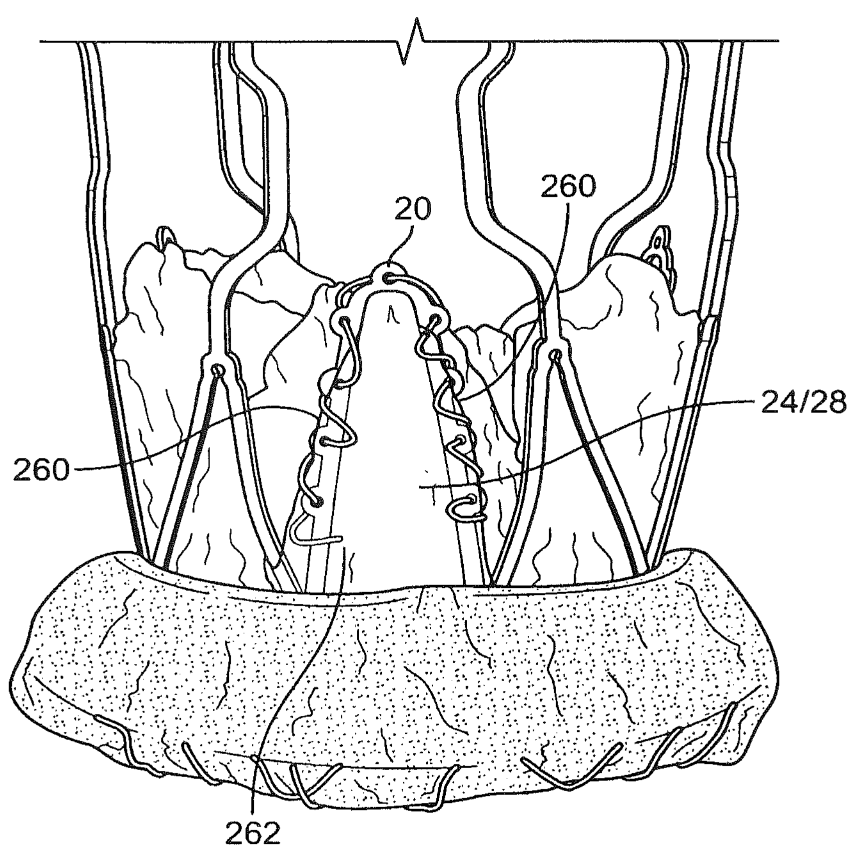


FIG. 49

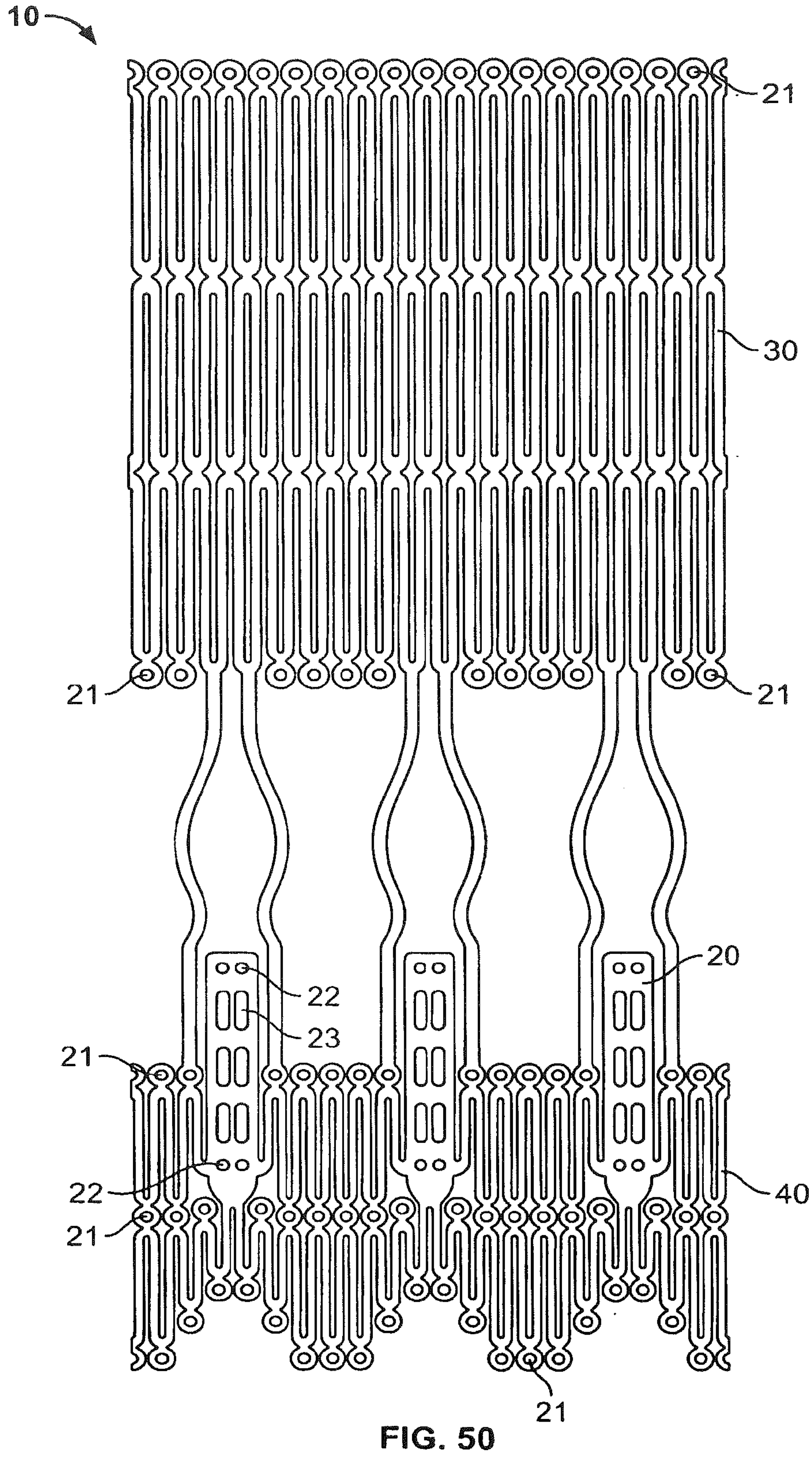


FIG. 50

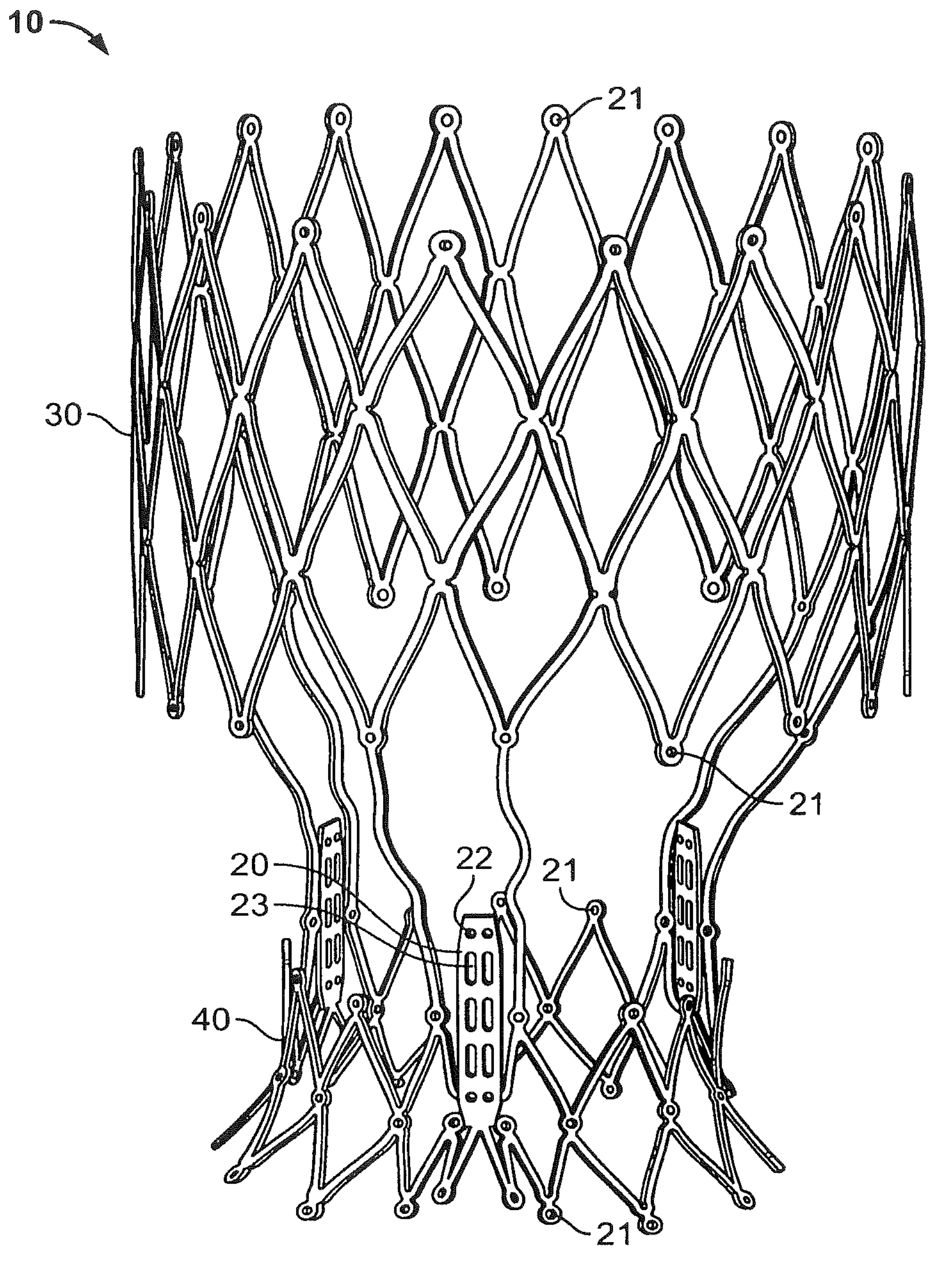


FIG. 51

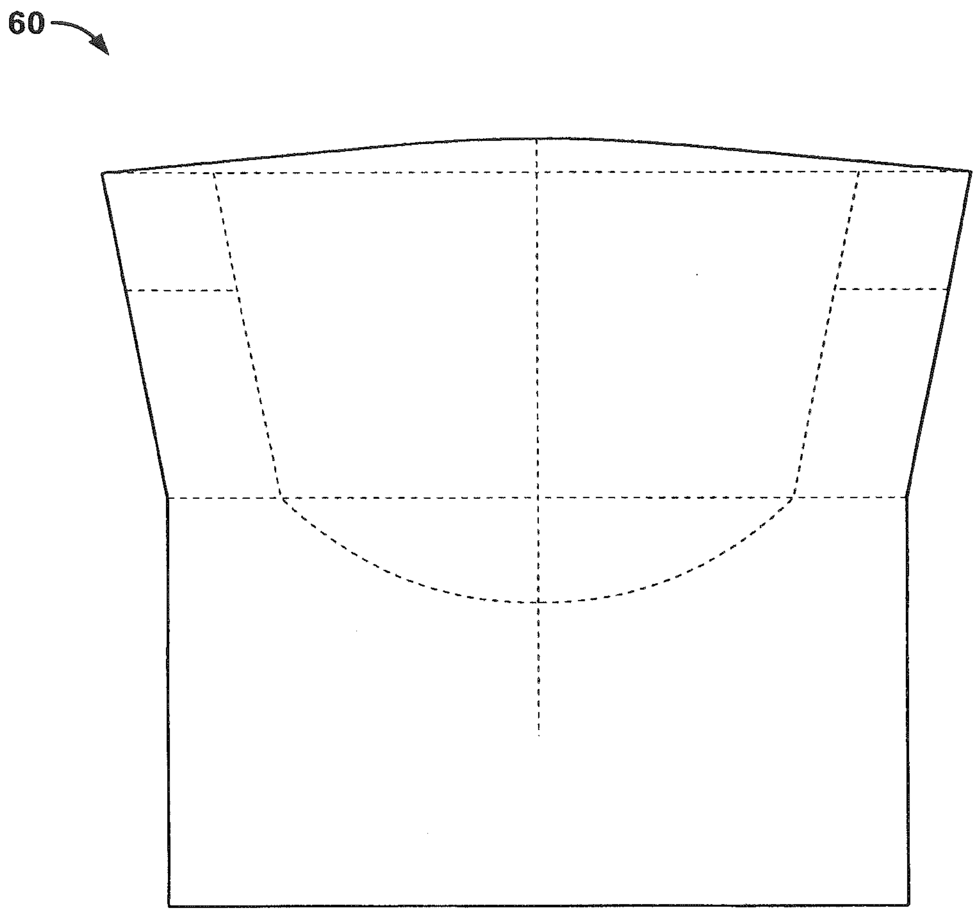


FIG. 52

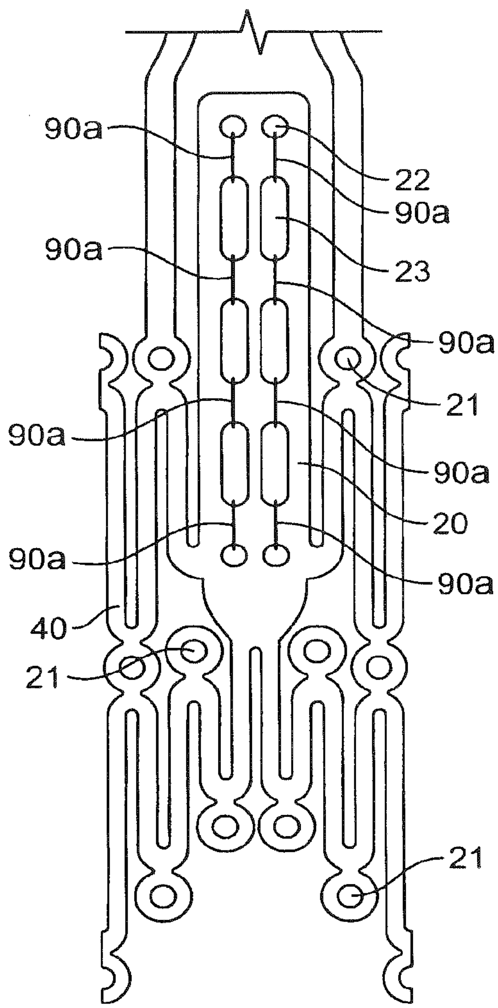


FIG. 53A

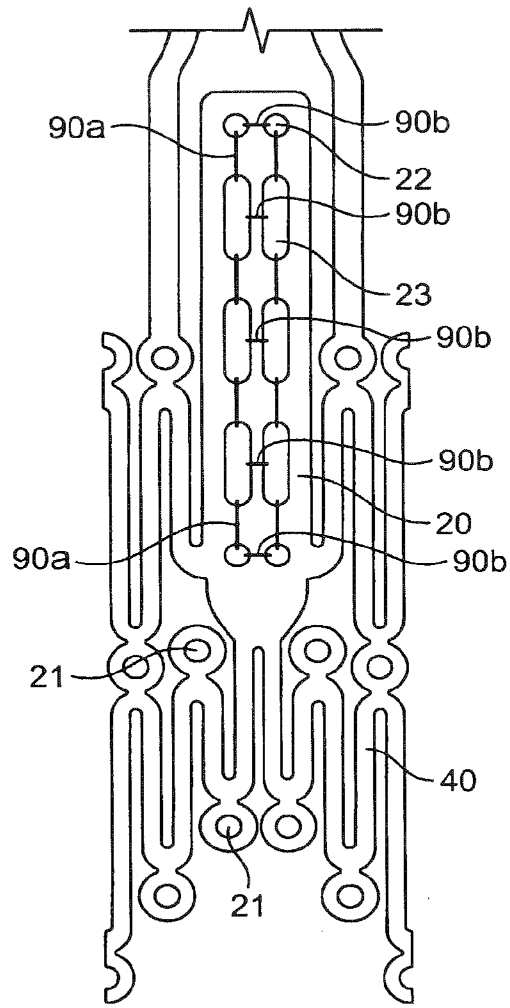


FIG. 53B

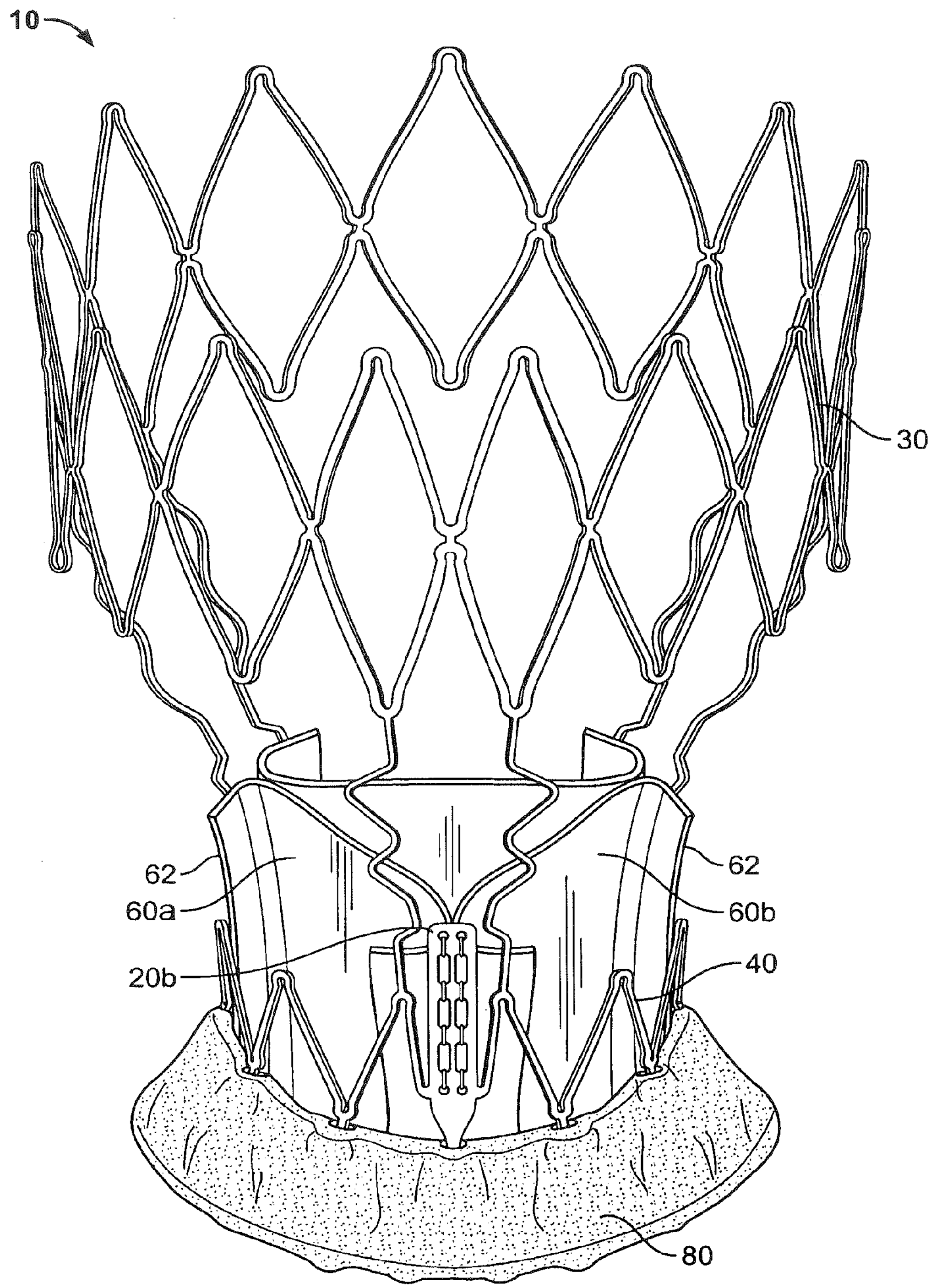


FIG. 54

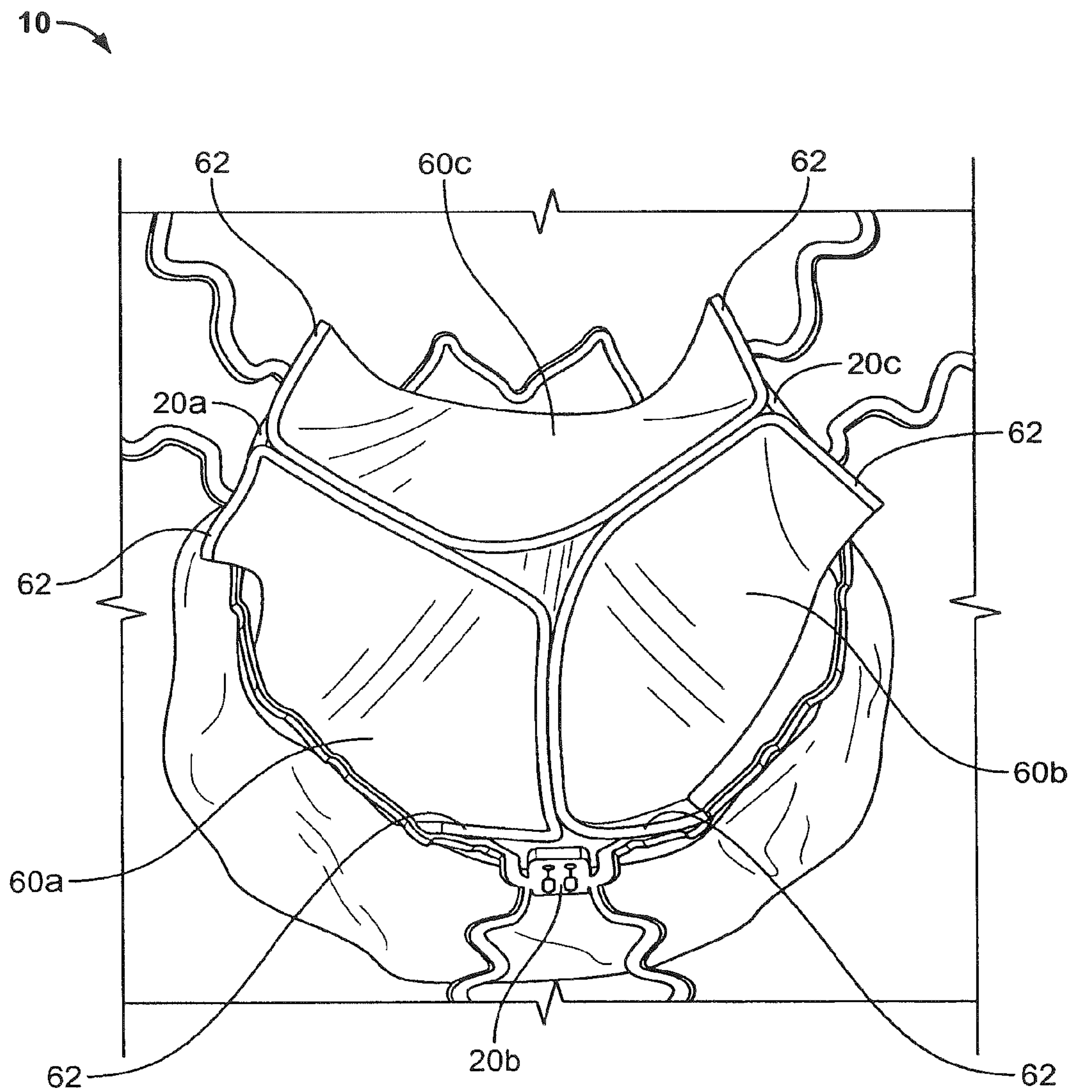


FIG. 55

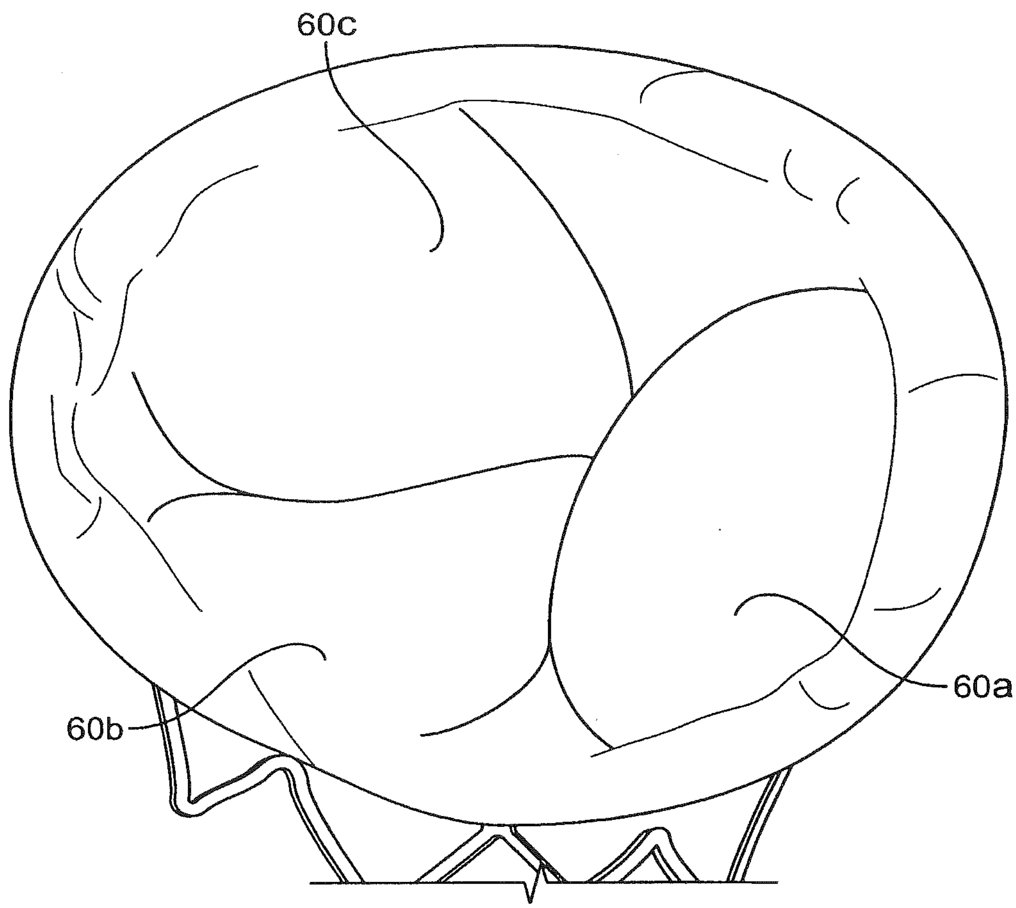


FIG. 56

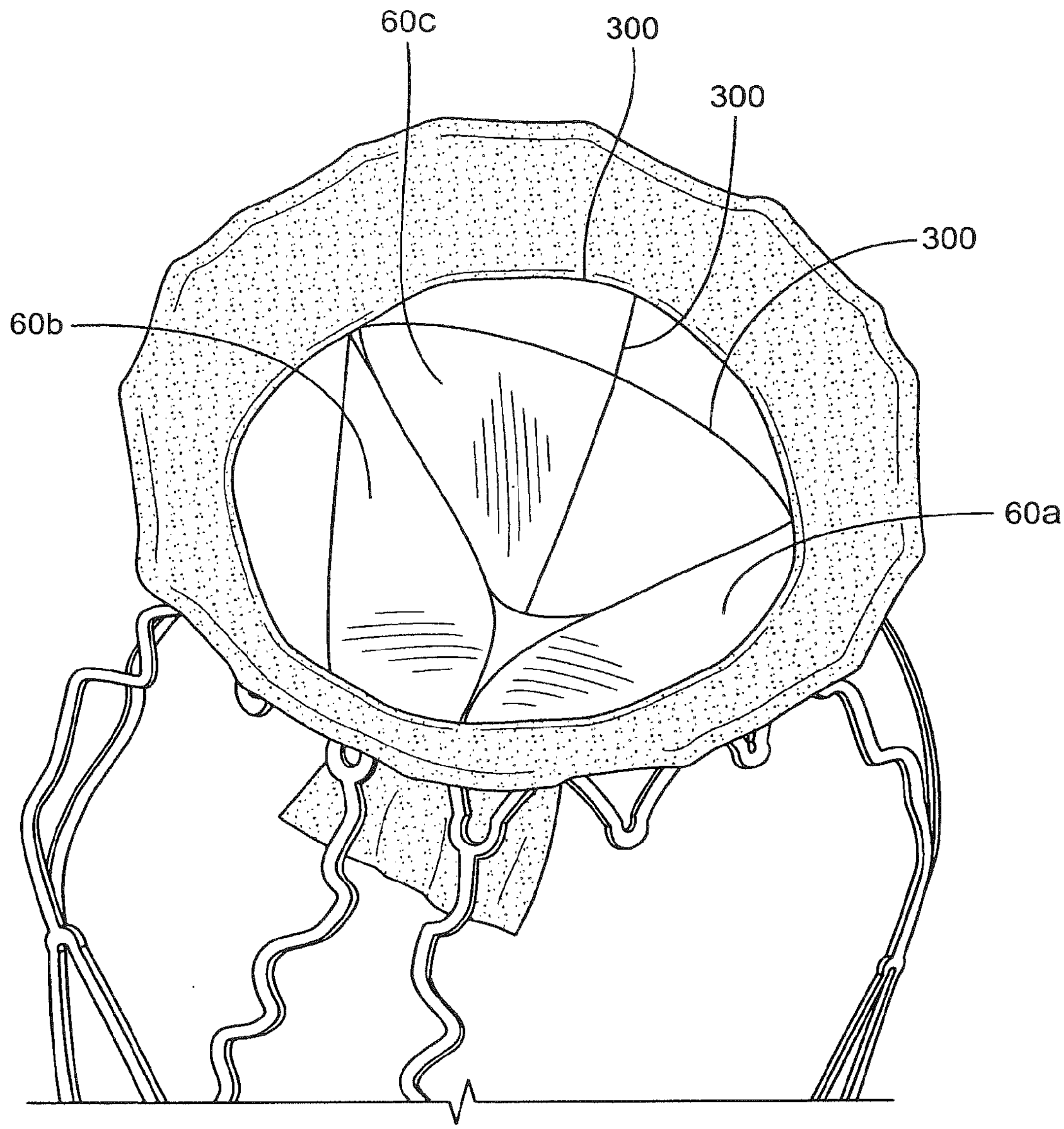


FIG. 57

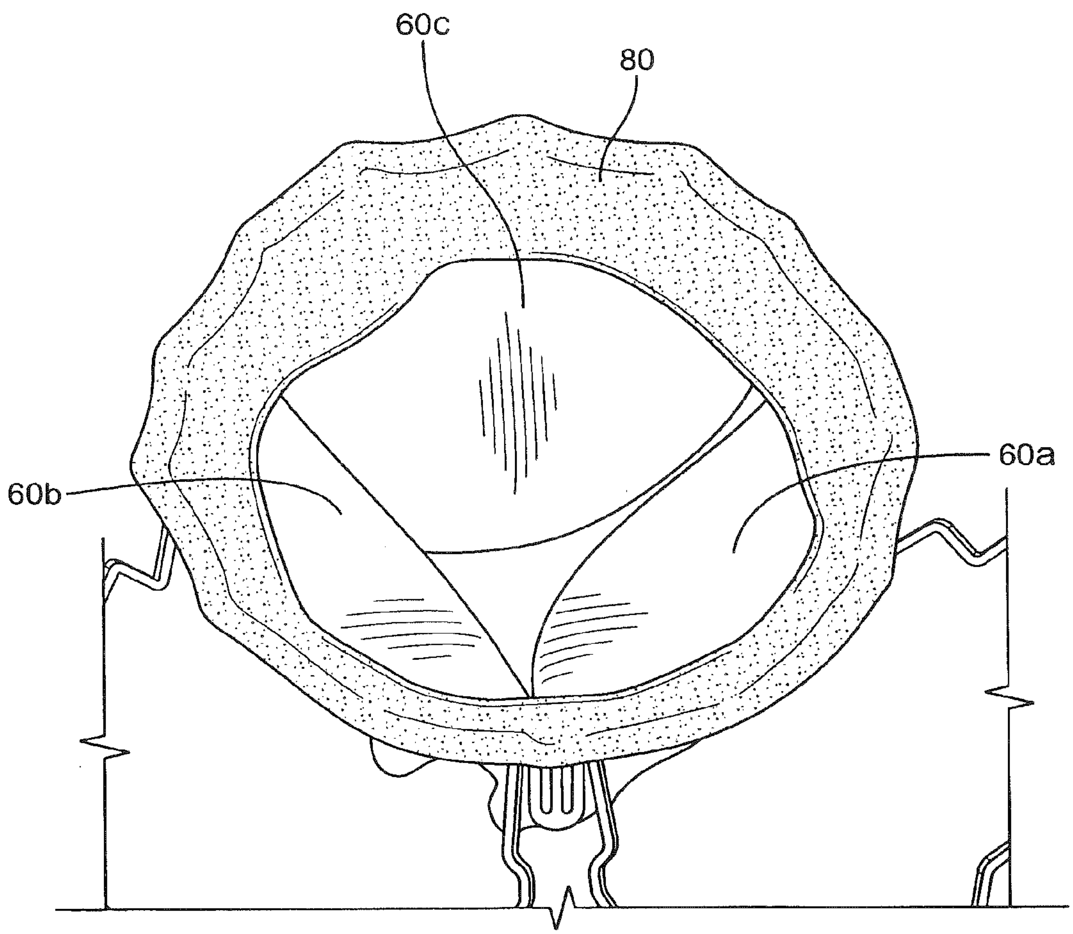


FIG. 58

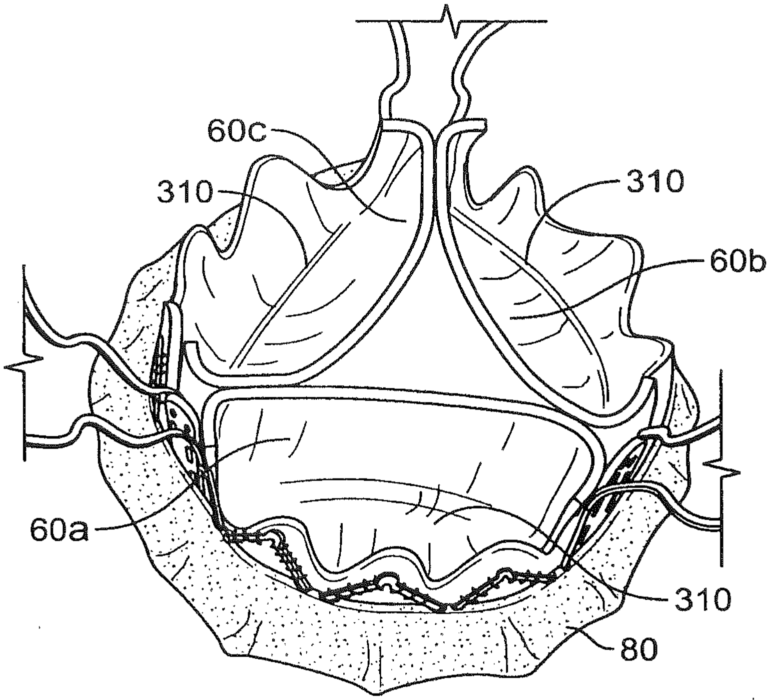


FIG. 59

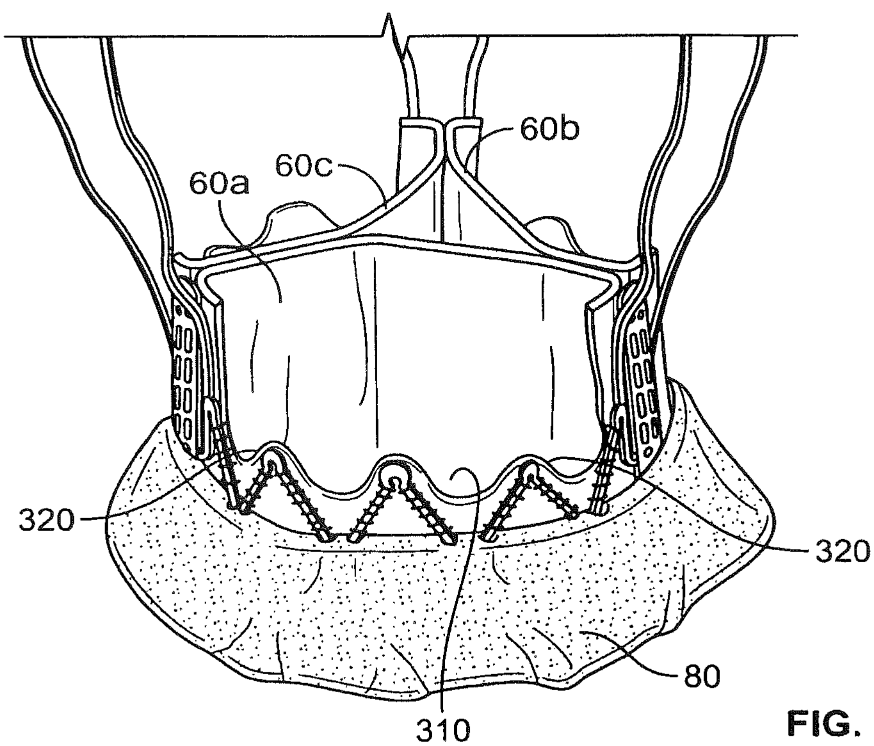


FIG. 60

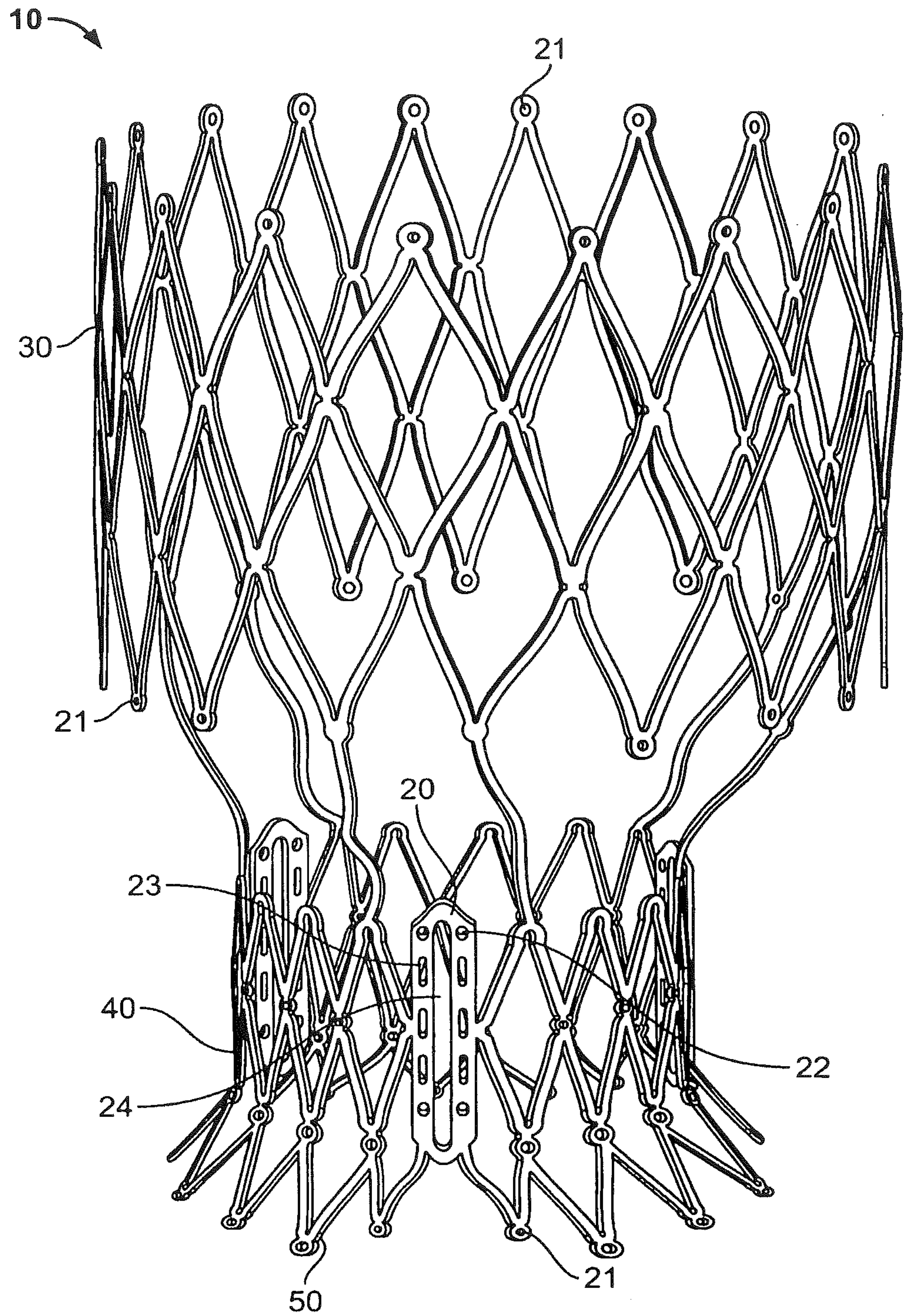


FIG. 61

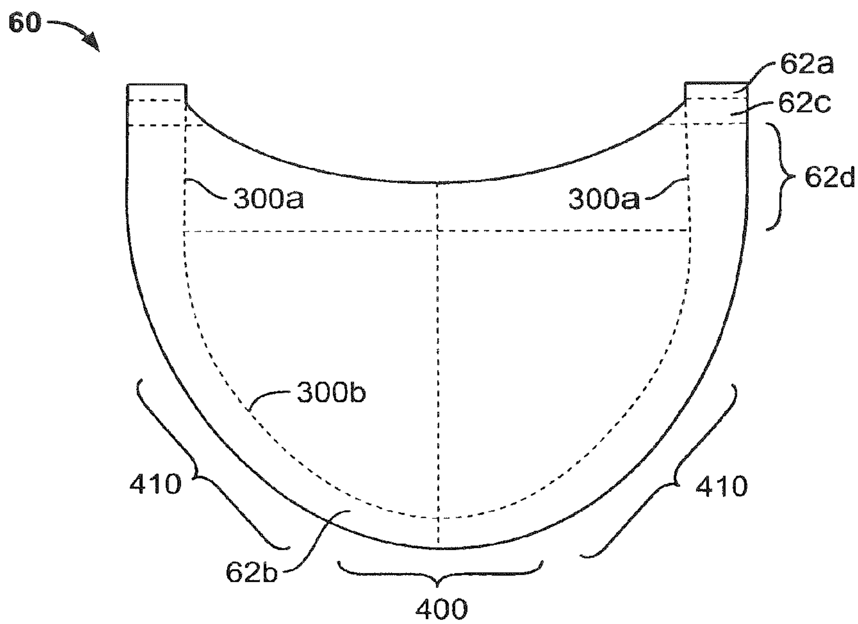
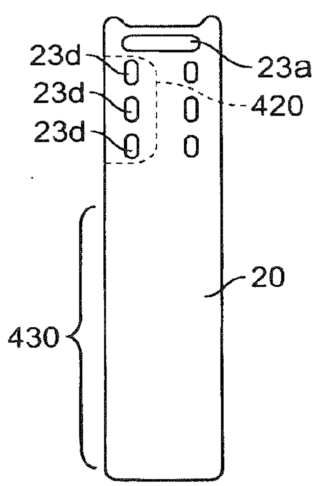


FIG. 62



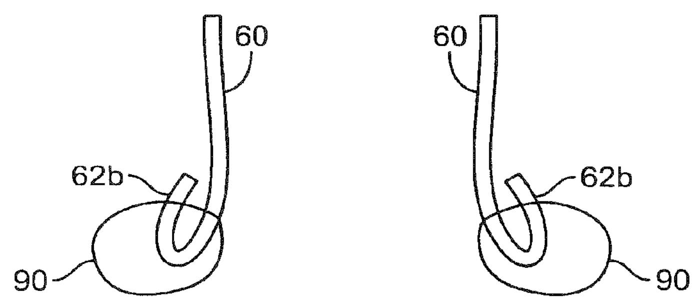


FIG. 64

FIG. 63

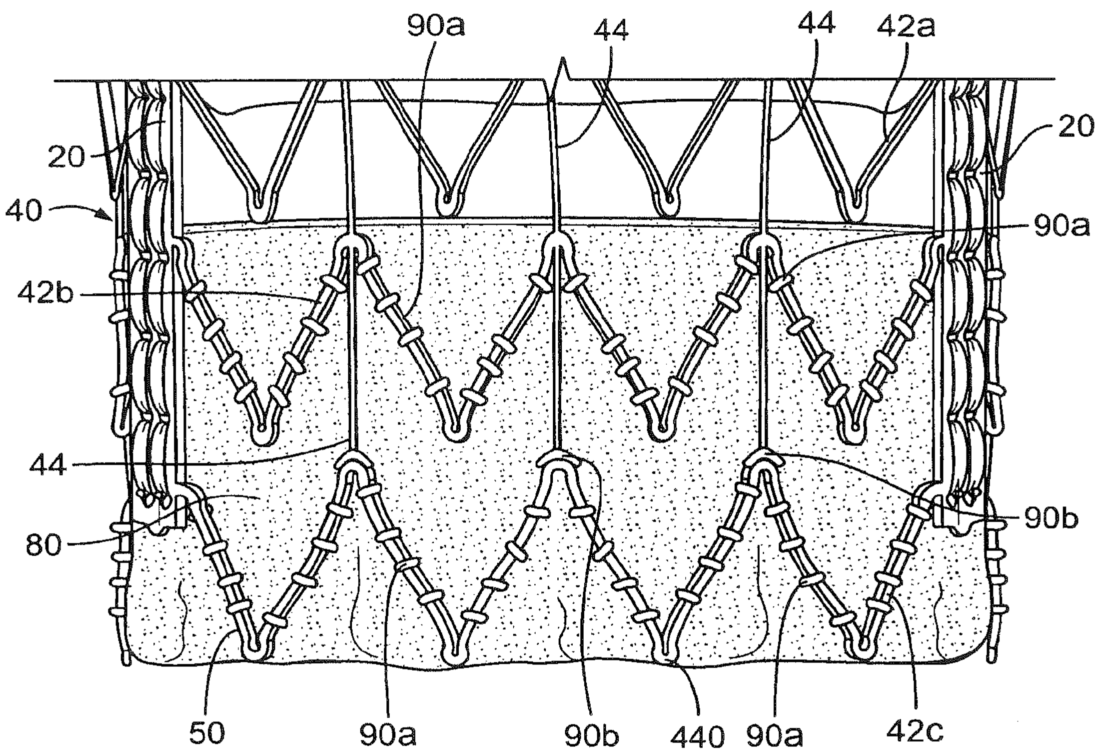


FIG. 65

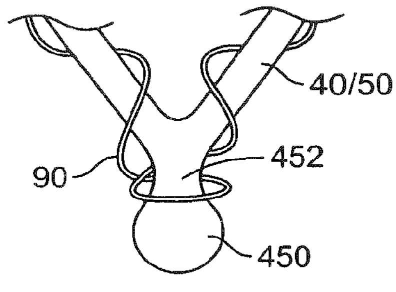


FIG. 66

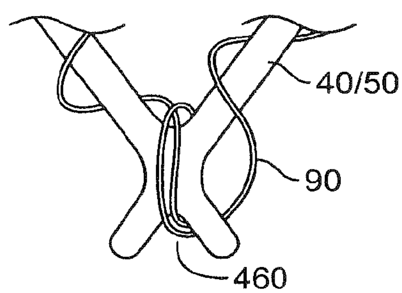


FIG. 67

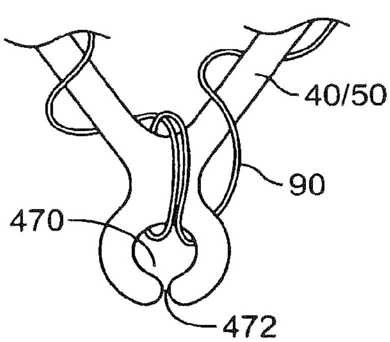


FIG. 68A

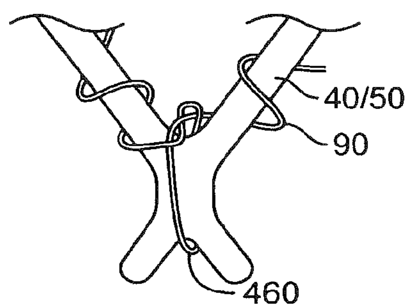


FIG. 68B

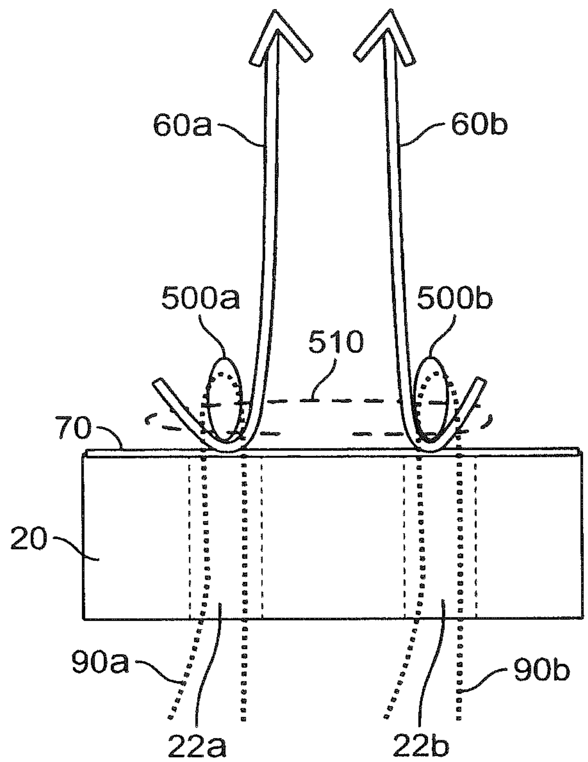


FIG. 69A

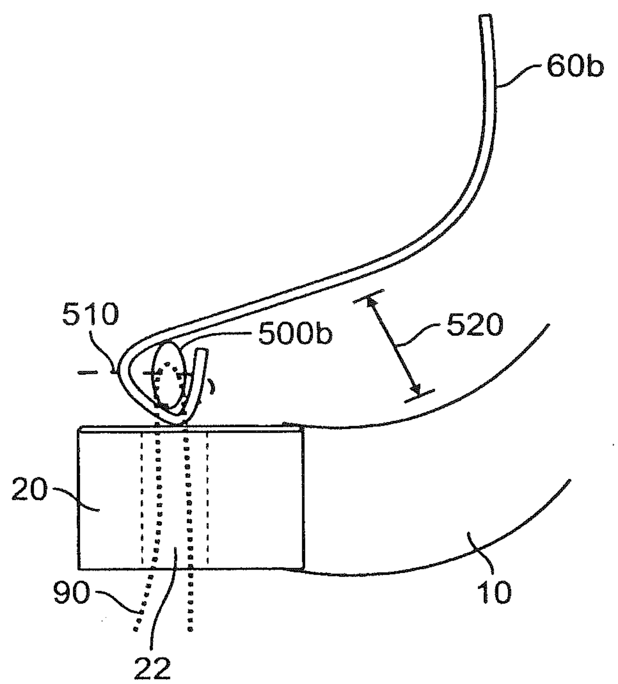


FIG. 69B

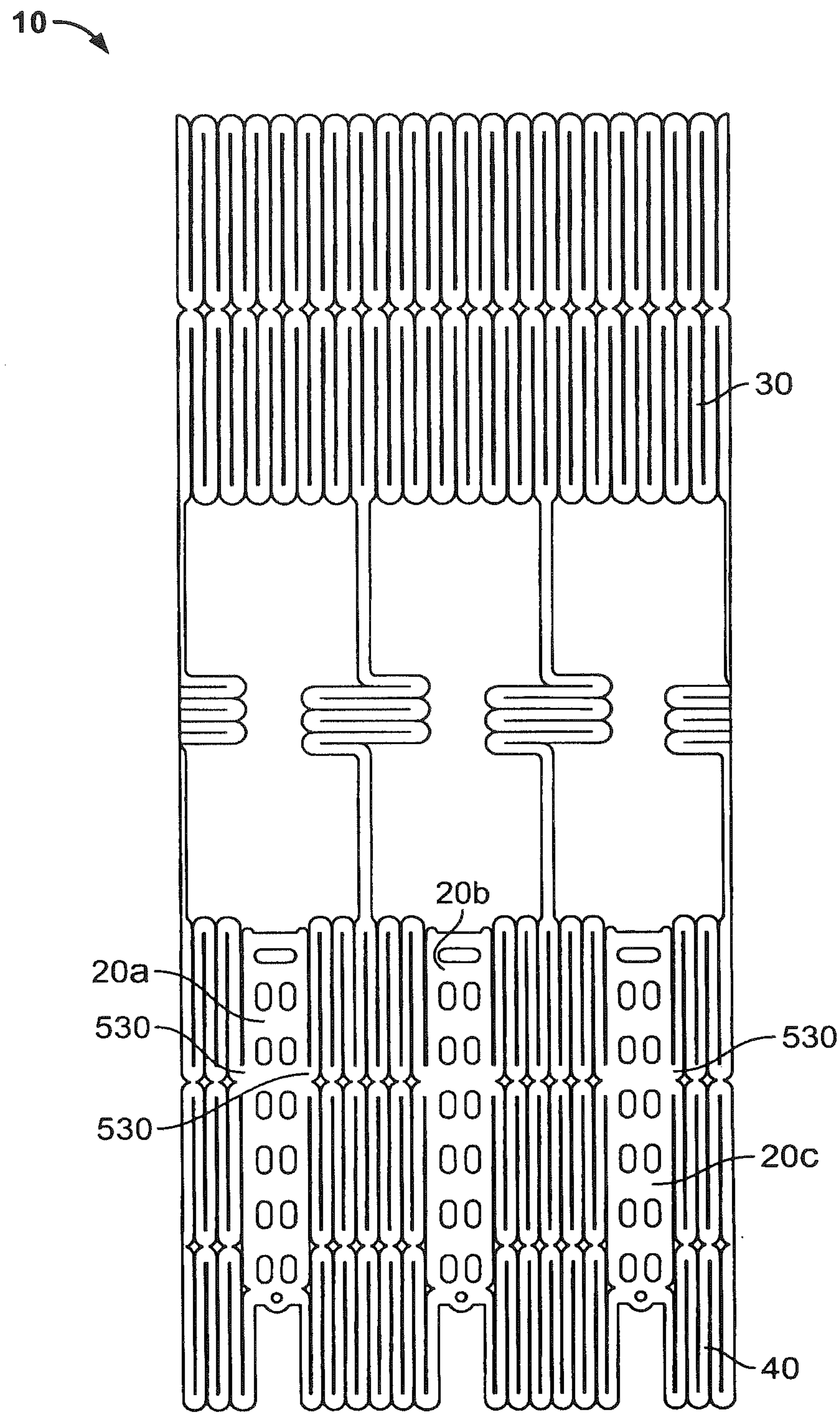


FIG. 70

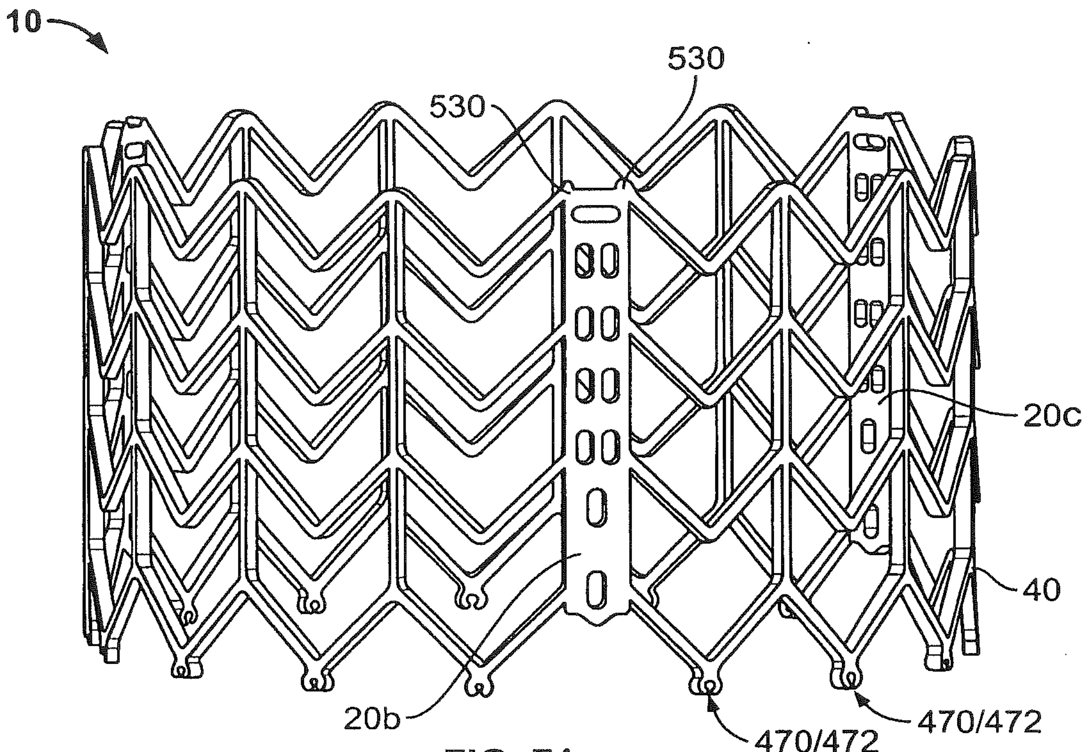


FIG. 71

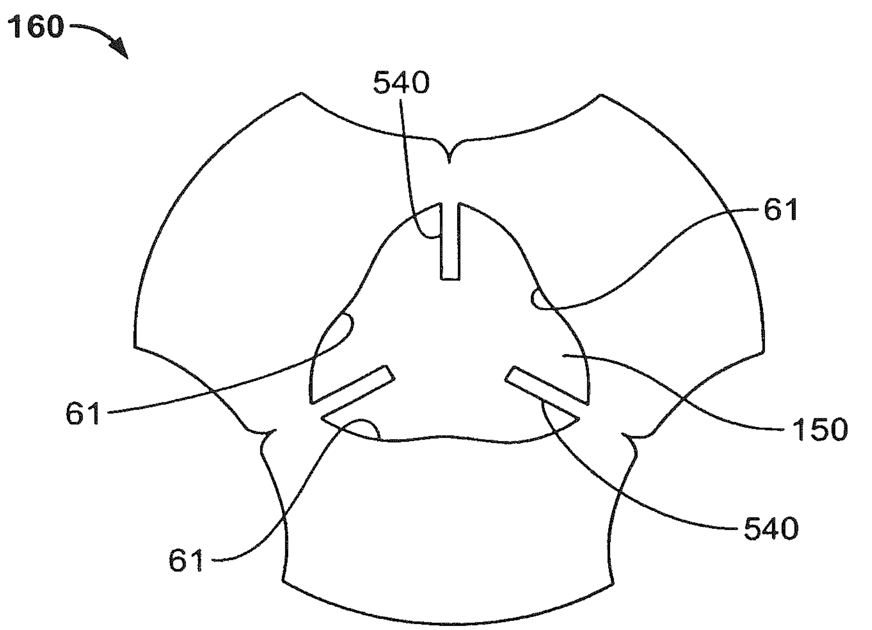


FIG. 72

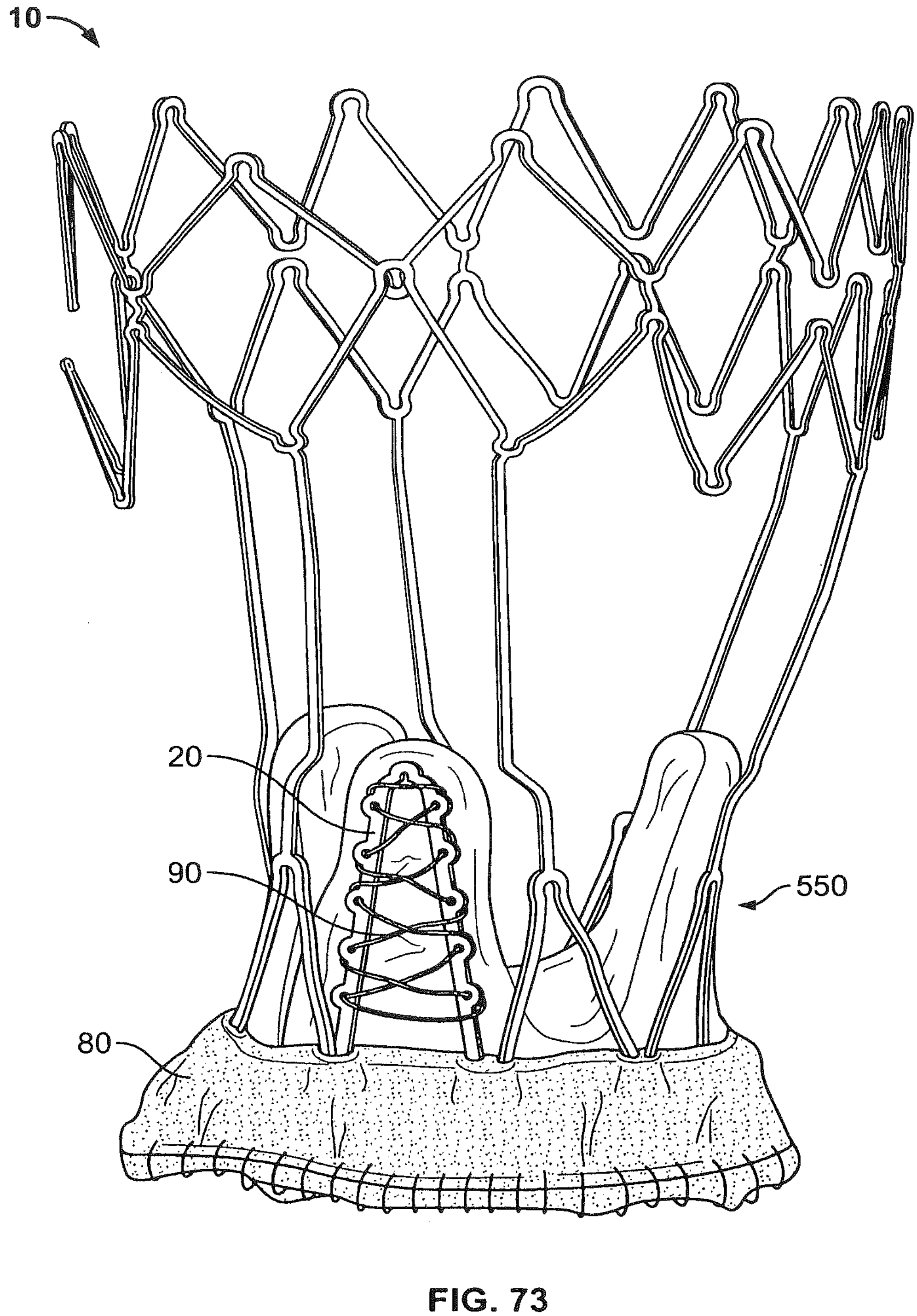


FIG. 73

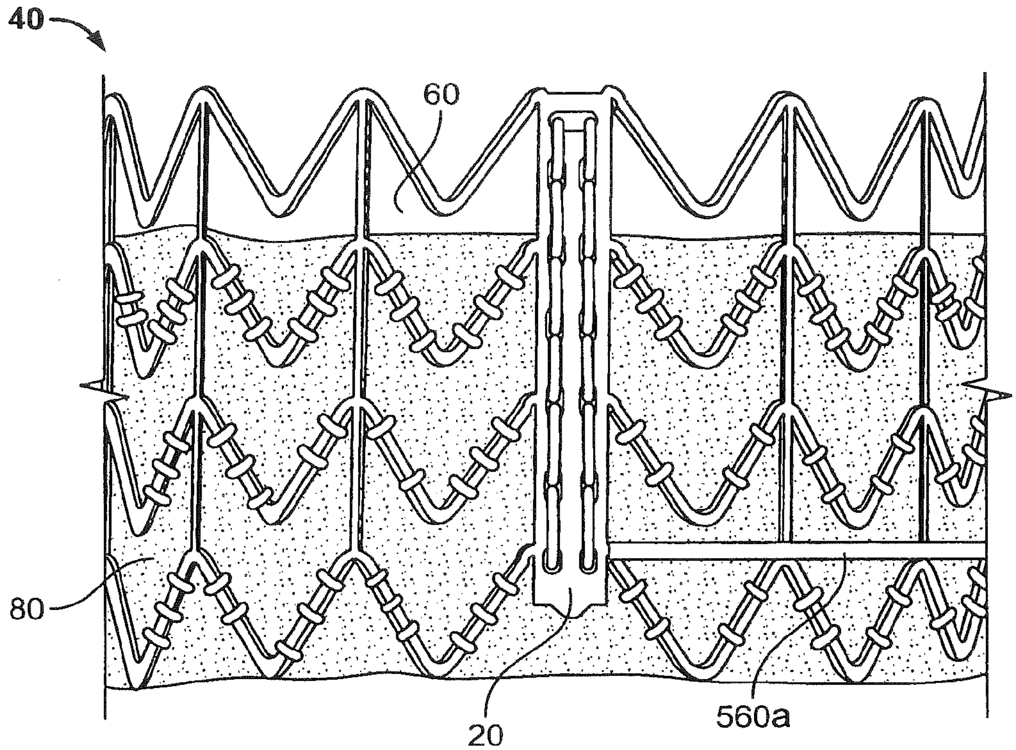


FIG. 74A

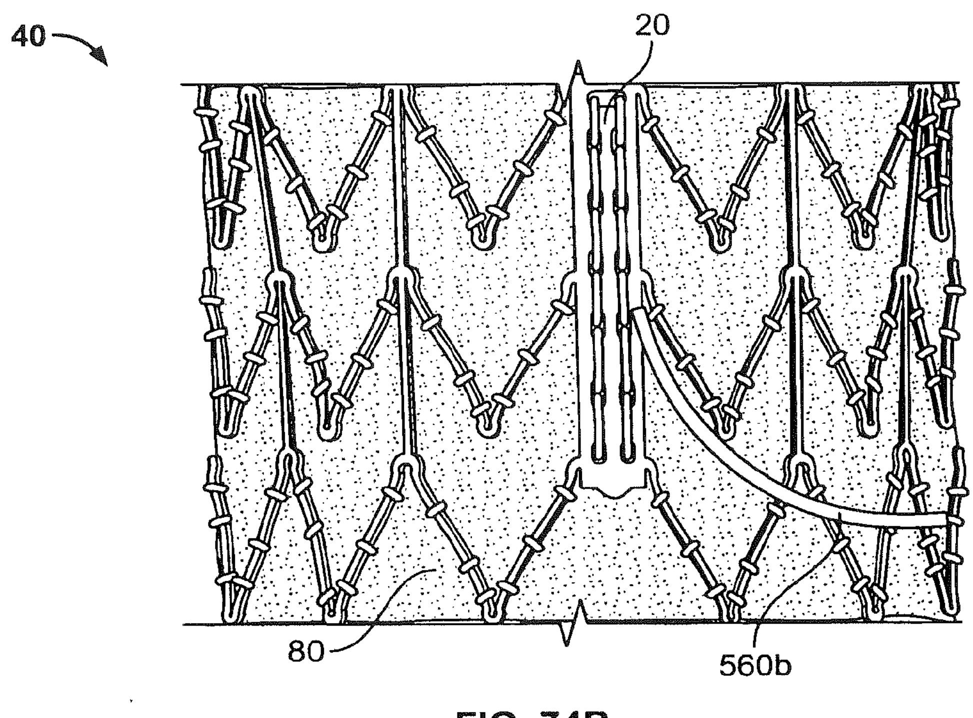


FIG. 74B

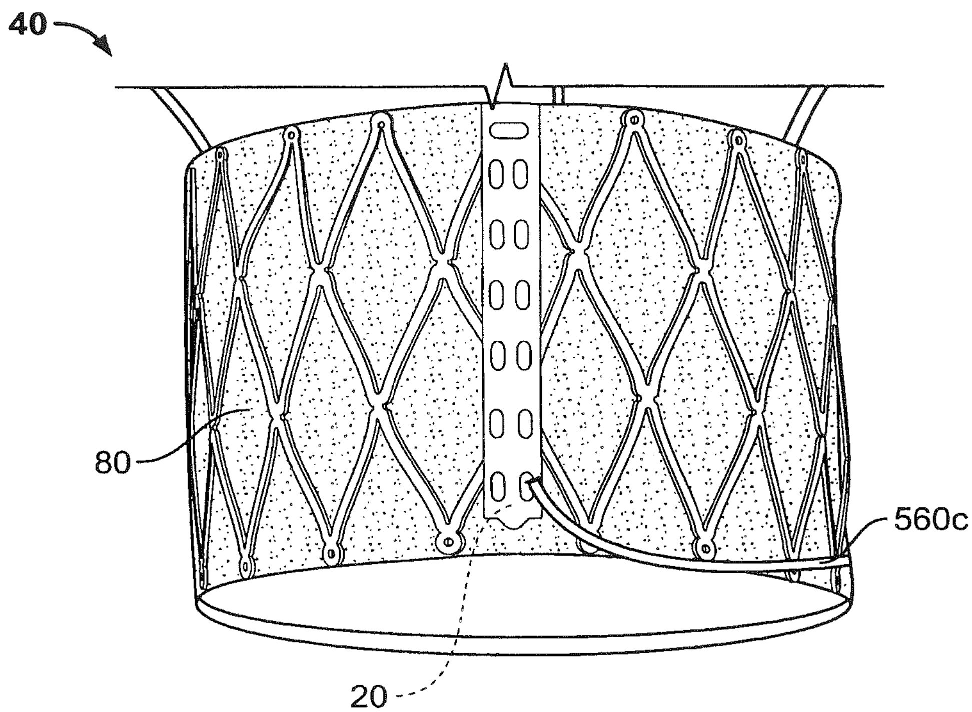


FIG. 74C

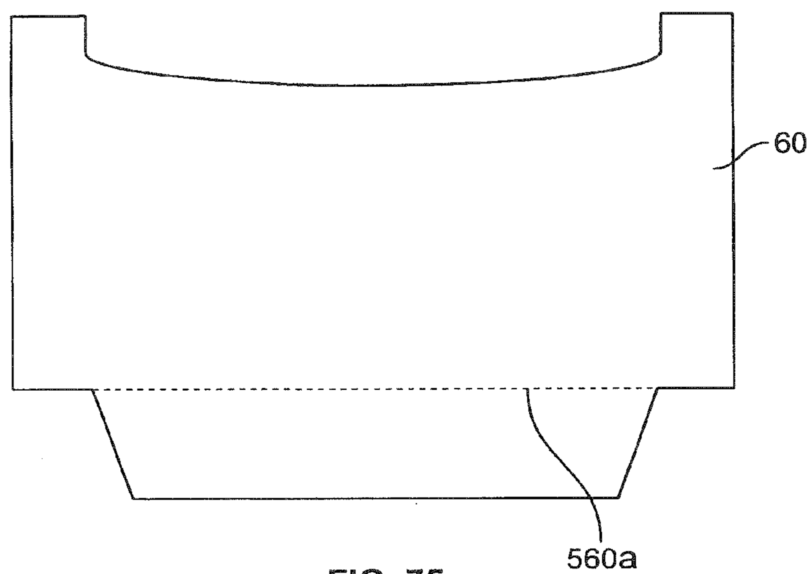


FIG. 75

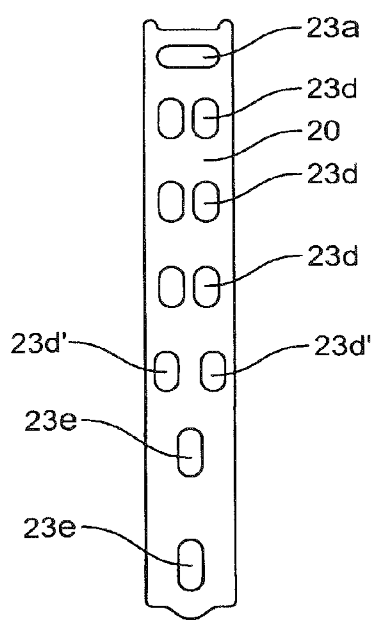


FIG. 76A

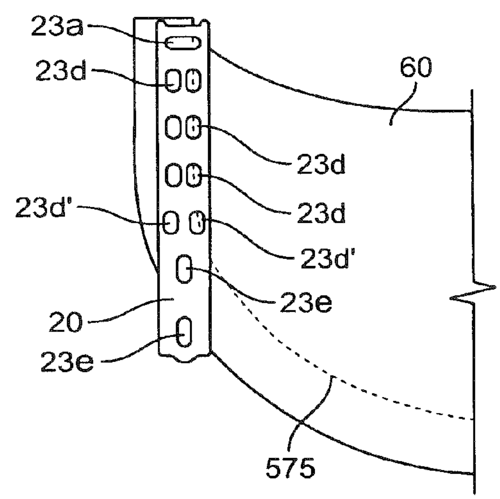


FIG. 76B

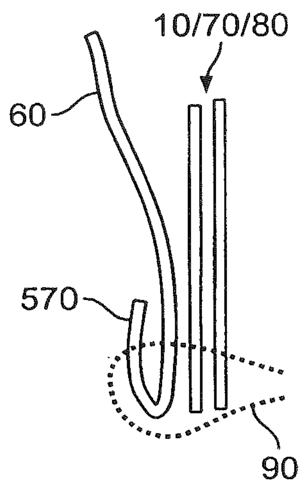


FIG. 77A

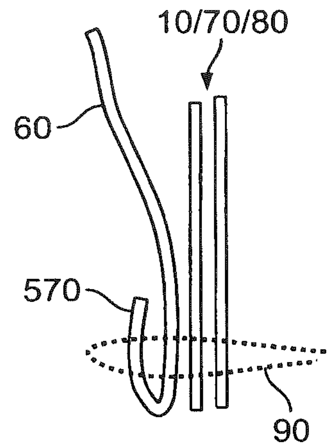


FIG. 77B

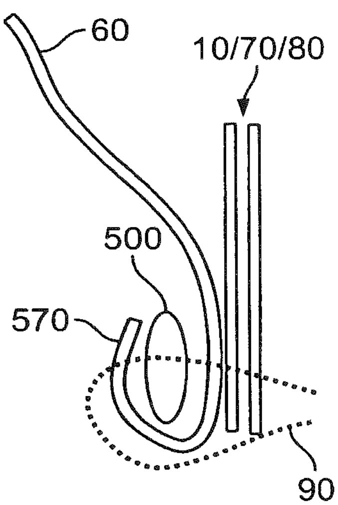


FIG. 77C

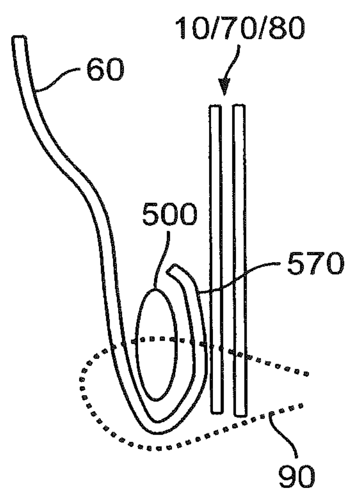


FIG. 77D

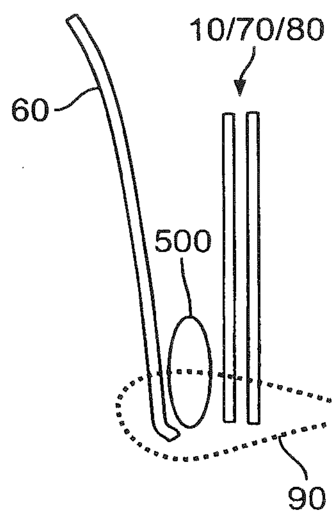


FIG. 77E

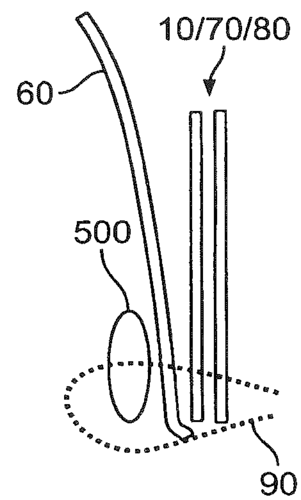


FIG. 77F

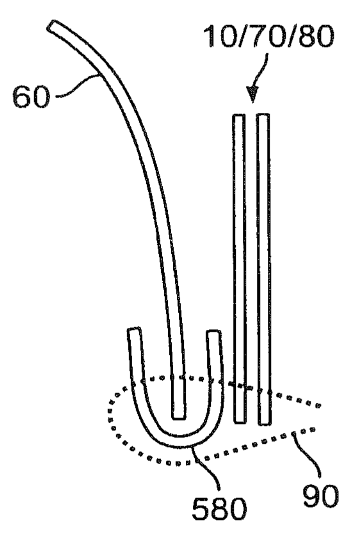


FIG. 77G

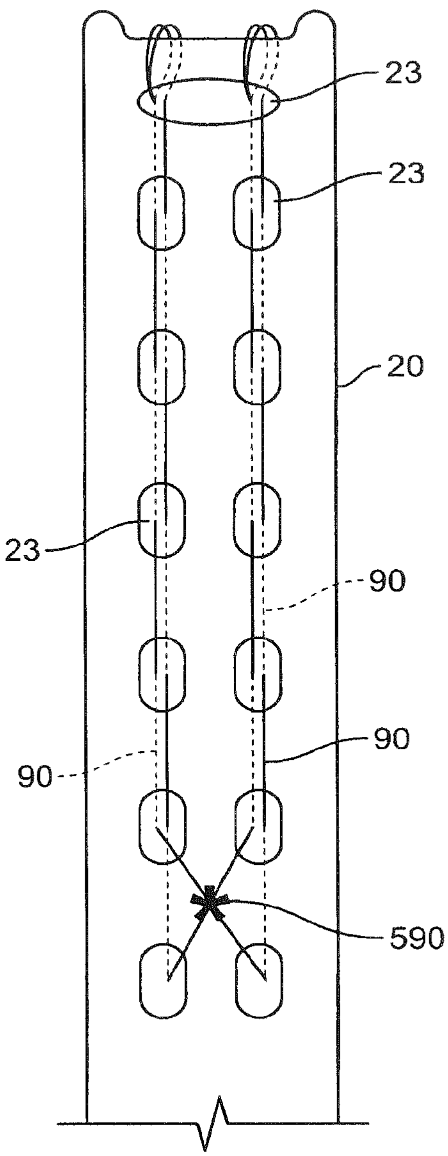


FIG. 78A

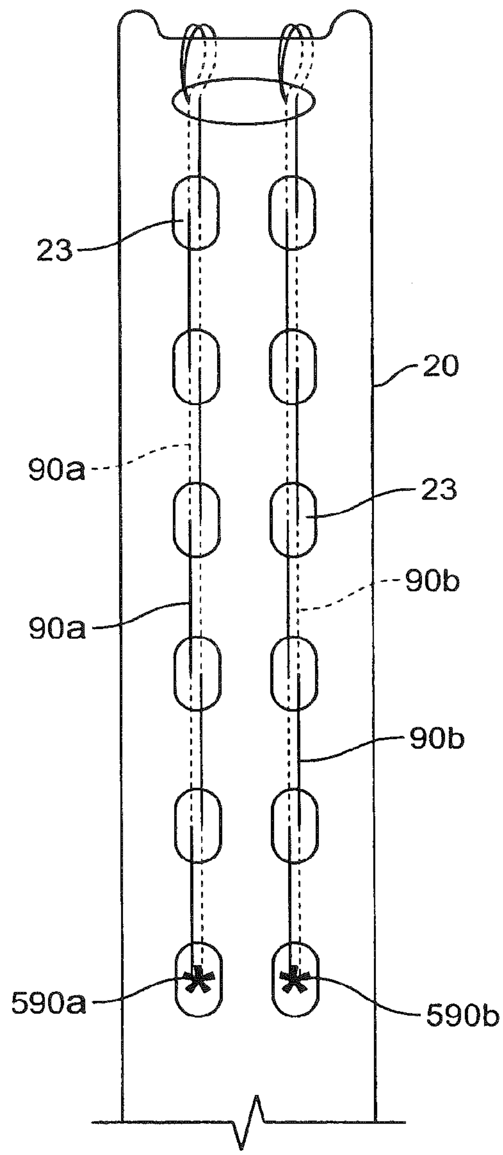


FIG. 78B

COLLAPSIBLE PROSTHETIC HEART VALVES

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13,848,466, filed Mar. 21, 2013, which is a continuation of Ser. No. 12/733,759, filed Mar. 18, 2010, now U.S. Pat. No. 8,425,593, which is a national phase entry under 35 U.S.C. §371 of International Application No. PCT/US2008/011153 filed Sep. 26, 2008, published in English, which claims the benefit of U.S. Provisional Application No. 60/995,648 filed Sep. 26, 2007, all of which are hereby incorporated herein by reference.

BACKGROUND OF THE INVENTION

Current collapsible prosthetic heart valve designs are for use within patients who may need a valve replacement (e.g., an aortic valve replacement), but who are not treated adequately by other means. A collapsible prosthetic heart valve is designed to be delivered into the patient in a collapsed condition via tube-like delivery apparatus. In the collapsed condition the valve has a reduced annular, radial, or circumferential size. Delivery of the valve into the patient can be less invasive than traditional open-chest/open-heart surgery. When the valve reaches the intended implant site in the patient, the valve re-expands or is expanded (e.g., balloon expanded) to operating size. The collapsing and re-expansion of the valve are preferably elastic, but may alternatively be plastic, the result of shape-memory properties of certain components of the valve, or various combinations of elastic, plastic, and/or shape-memory. Again, plastic expansion may be as a result of inflation of a balloon that is temporarily disposed inside the valve. Known designs of this general kind can be implanted percutaneously, trans-apically, or surgically, with or without resected and/or debrided native heart valve leaflets.

SUMMARY OF THE INVENTION

The prosthetic heart valves disclosed herein incorporate a collapsible valve (which may or may not include independently flexing commissure posts) and unique ways in which to assemble the leaflets and ancillary components.

In accordance with certain possible aspects of the invention, a prosthetic heart valve may include an annular, annularly collapsible and re-expandable supporting structure, and a sheet-like, flexible, leaflet member mounted inside the supporting structure so that a free edge portion of the leaflet forms a flexible chord across an interior of the supporting structure. Material of the leaflet may extend beyond an end of the chord and form a flap that is folded to lie, at least in part, in a cylindrical surface defined by one of the inner and outer surfaces of the supporting structure.

The above-mentioned flap may be secured to the supporting structure. For example, the flap may be sutured to the supporting structure to secure the flap to the supporting structure. As a more particular example, the flap may lie, at least in part, in the cylindrical surface defined by the inner surface of the supporting structure. Alternatively, the flap may pass through the supporting structure to lie, at least in part, in the cylindrical surface defined by the outer surface of the supporting structure.

The leaflet may have a secured line portion which is spaced from the free edge portion across an intervening belly portion

of the leaflet. The secured line portion may be secured to the supporting structure, and additional material of the leaflet beyond the secured line portion away from the belly portion may form a second flap that is folded to lie, at least in part, in a cylindrical surface defined by one of the inner and outer surfaces of the supporting structure.

The above-mentioned second flap may be folded toward the free edge portion of the leaflet and secured to the supporting structure inside the supporting structure. Alternatively, the second flap may be folded away the free edge portion and secured to the supporting structure inside the supporting structure. Especially in the latter case, the second flap may continue beyond an axial end of the supporting structure and may be additionally folded over that axial end and back outside of the supporting structure for additional securement to the outside of the supporting structure.

A prosthetic heart valve in accordance with the invention may additionally include sheet-like, flexible, buffer material between the supporting structure and the leaflet. Buffer material can alternatively be provided so that it only outlines (covers) certain members of the supporting structure, instead of forming a more extensive continuous sheet that covers not only members of the supporting structure but also otherwise open cells of that structure. For example, such outlining or less extensive buffer material can be a dip-coated or sprayed-on polymer.

The supporting structure of a prosthetic heart valve in accordance with the invention may include a plurality of annularly spaced commissure posts, each of which may be cantilevered from other structure of the supporting structure. The above-mentioned flap that extends beyond an end of the above-mentioned free edge chord of the leaflet may be secured to an associated one of the commissure posts. For example, this securement may be by suture material that passes through the flap and apertures through the associated commissure post. The flap may be folded around the associated commissure post. The associated commissure post may be bifurcated into two spaced apart members. The flap may pass through the commissure post between those two members.

In accordance with another possible aspect of the invention, the supporting structure may include a plurality of annular, annularly collapsible and re-expandable substructures that are spaced from one another along an axis about which the supporting structure is annular. The supporting structure may further include a plurality of linking members that are substantially parallel to the above-mentioned axis and that interconnect the substructures without the linking members deforming when the substructures annularly collapse and re-expand.

In accordance with yet another possible aspect of the invention, a leaflet structure for a prosthetic heart valve may include a sheet of flexible leaflet material having a central opening with three sides, each of the sides being shaped to form the free edge of a respective one of three operating leaflet portions of the leaflet structure. The sheet may additionally have three secured line portions, each of which is radially outward from a respective, associated one of the free edges, and each of which is arcuate so that it is radially farther from a midpoint of the associated free edge than from endpoints of the associated free edge.

The above-mentioned sheet may define three leaflet-linking areas, each of which extends from a junction of a respective pair of the free edges to a junction of the secured line portions that are radially outward from the free edges in that pair.

For use of the above-mentioned sheet, a prosthetic heart valve in accordance with the invention may include an annular, annularly collapsible and re-expandable supporting structure. The above-mentioned sheet may then be disposed in the supporting structure with the secured line portions and the leaflet-linking areas secured to the supporting structure so that the free edges can come together in the interior of the supporting structure. The supporting structure may include three annularly spaced commissure posts, each of which may or may not be cantilevered from other structure of the supporting structure. Each of the leaflet-linking areas may be secured to a respective one of the commissure posts. At least one of the leaflet-linking areas may pass outside the supporting structure at the commissure post to which that leaflet-linking area is secured. At least one of the commissure posts may be bifurcated into two spaced apart members, and the leaflet-linking area that is secured to that commissure post may pass between the two members of that commissure post.

The above-mentioned sheet may continue radially outwardly beyond at least a portion of at least one of the secured line portions to form a flap. In use of the sheet in a prosthetic heart valve that includes a supporting structure as mentioned above, such a flap may be secured to the supporting structure. For example, the flap may be secured inside the supporting structure. Alternatively, the flap may be secured outside the supporting structure.

As another possibility, in use of the above-mentioned sheet in a prosthetic heart valve that includes a supporting structure (as also mentioned above), the valve may also include sheet-like, flexible, buffer material between the supporting structure and the leaflet material.

In accordance with other possible aspects of the invention, a prosthetic heart valve may include an annular, annularly collapsible and re-expandable supporting structure, which in turn includes a plurality of members disposed in a zig-zag pattern that extends in a direction that is annular of the supporting structure. At least two of the members forming such a zig-zag pattern meet at an apex that points away from the supporting structure parallel to an axis about which the supporting structure is annular. The valve may further include a sheet of flexible material secured to the supporting structure, and a plurality of flexible leaflets disposed inside the supporting structure and at least partly secured to the sheet. The sheet may be at least partly secured to the supporting structure via a suture attachment at the apex. The apex may be shaped to prevent the suture attachment from moving away from the apex in a direction opposite to a direction in which the apex points.

As a specific example, the above-mentioned apex may include an eyelet through which the suture attachment passes. As another example, the apex may include an enlarged head on the end of a reduced neck that extends in the direction that the apex points, and a suture attachment for the above-mentioned sheet may be wound around the neck. As still another example, the apex may comprise a notch that opens in the direction that the apex points, and the above-mentioned suture attachment may be wound around the inside of the apex and the inside of the notch. The above-mentioned notch may be narrowed near its entrance to form an open eyelet. Such an open eyelet may be too small for passage of a suture needle, but the entrance may be large enough for suture material to slip through.

Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a simplified elevational view of an illustrative embodiment of a component that can be used in prosthetic heart valves in accordance with the invention.

FIG. **1**B is an isometric or perspective view of what is shown in FIG. **1**A.

FIG. **2**A is a simplified elevational view of an alternative embodiment of what is shown in FIG. **1**A. FIG. **2**A shows only the foreground portion of the depicted component.

FIG. **2**B is similar to FIG. **2**A, but from a different angle and with parts of the background structure shown in addition to the foreground structure.

FIG. **3**A is similar to FIG. **2**A, but with illustrative additional components added.

FIG. **3**B is similar to FIG. **3**A, but with illustrative, still further components added.

FIG. **4**A is a flat development of an illustrative embodiment of what is actually a cylindrical component, which can be used in prosthetic heart valves in accordance with the invention.

FIG. **4**B is an elevational view of the cylindrical component that is shown in flat-development form in FIG. **4**A.

FIG. **5**A is similar to FIG. **4**A for another illustrative embodiment.

FIG. **5**B is an enlargement of a portion of FIG. **5**A.

FIG. **6** is an elevational view of an illustrative embodiment of another component that can be used in prosthetic heart valves in accordance with the invention.

FIG. **7** is similar to FIG. **6** for another illustrative embodiment.

FIG. **8** is similar to FIG. **7** for still another illustrative embodiment.

FIG. **9** is similar to FIG. **8** for yet another illustrative embodiment.

FIG. **10** is an elevational view of an illustrative embodiment of still another component that can be used in prosthetic heart valves in accordance with the invention.

FIG. **11** is a simplified perspective view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **12**A is a simplified, partial, top view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **12**B is similar to FIG. **12**A for another illustrative embodiment.

FIG. **12**C is similar to FIG. **12**B for still another illustrative embodiment.

FIGS. **13** and **14** are each generally similar to FIG. **11**.

FIG. **15**A is a simplified, partial, elevational view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **15**B is another view of the same general kind as FIG. **15**A.

FIG. **16** is a bottom view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **17** is similar to FIG. **5**B for another illustrative embodiment.

FIG. **18**A is a simplified isometric or perspective view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **18**B is a simplified, partial, elevational view of an illustrative embodiment of several components in accordance with the invention.

FIG. **19** is similar to FIG. **10** for another illustrative embodiment.

FIG. **20**A is a simplified, partial, top view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **20**B is a simplified sectional view of part of what is shown in FIG. **20**A.

FIG. **21** is similar to FIG. **19** for another illustrative embodiment.

FIG. **22** is similar to FIG. **18**A for another illustrative embodiment.

FIG. **23**A is similar to FIG. **12**C for another illustrative embodiment.

FIG. **23**B is similar to FIG. **23**A for another illustrative embodiment.

FIG. **24**A is similar to FIG. **5**A for another illustrative embodiment.

FIG. **24**B is similar to FIG. **5**B for another illustrative embodiment.

FIGS. **25**A and **25**B are each similar to FIG. **21** for other illustrative embodiments.

FIGS. **26**A and **26**B are each similar to FIG. **23**B for other illustrative embodiments.

FIG. **27** is similar to FIG. **22** for another illustrative embodiment.

FIG. **28** is similar to FIG. **24**B for another illustrative embodiment.

FIGS. **29**A and **29**B are respectively similar to FIGS. **24**A and **24**B for another illustrative embodiment.

FIG. **30** is similar to FIG. **1**A for another illustrative embodiment.

FIG. **31** is similar to FIG. **29**B for another illustrative embodiment.

FIG. **32** is similar to FIG. **8** for another illustrative embodiment.

FIGS. **33**A and **33**B are each similar to FIG. **25**B for other illustrative embodiments.

FIG. **34** is similar to FIG. **26**B for another illustrative embodiment.

FIGS. **35**A and **35**B are each similar to FIG. **15**B for another illustrative embodiment.

FIG. **36** is similar to FIG. **21** for another illustrative embodiment.

FIG. **37** is similar to FIG. **34** for another illustrative embodiment.

FIGS. **38**A and **38**B are respectively similar to FIGS. **29**A and **29**B for another illustrative embodiment.

FIG. **39** is similar to FIG. **30** for another illustrative embodiment.

FIG. **40** is similar to FIG. **32** for another illustrative embodiment.

FIGS. **41**A and **41**B are each similar to FIG. **33**B for other illustrative embodiments.

FIG. **42** is similar to FIG. **37** for another illustrative embodiment.

FIG. **43** is similar to FIG. **35**B for another illustrative embodiment.

FIG. **44** is similar to FIG. **41**B for another illustrative embodiment.

FIG. **45** is similar to FIG. **42** for another illustrative embodiment.

FIG. **46** is similar to FIG. **43** for another illustrative embodiment.

FIG. **47** is similar to FIG. **36** for another illustrative embodiment.

FIG. **48** is similar to FIG. **5** for another illustrative embodiment.

FIG. **49** is similar to FIG. **46** for another illustrative embodiment.

FIG. **50** is similar to FIG. **38**A for another illustrative embodiment.

FIG. **51** is similar to FIG. **39** for another illustrative embodiment.

FIG. **52** is similar to FIG. **44** for another illustrative embodiment.

FIGS. **53**A and **53**B are each similar to FIG. **7** for other illustrative embodiments.

FIG. **54** is similar to FIG. **35**A for another illustrative embodiment.

FIG. **55** is similar to FIG. **13** for another illustrative embodiment.

FIG. **56** is similar to FIG. **16** for another illustrative embodiment.

FIG. **57** is similar to FIG. **56** for another illustrative embodiment.

FIG. **58** is similar to FIG. **57** for another illustrative embodiment.

FIG. **59** is similar to FIG. **55** for another illustrative embodiment.

FIG. **60** is similar to FIG. **54** for another illustrative embodiment.

FIG. **61** is similar to FIG. **51** for another illustrative embodiment.

FIG. **62** is similar to FIG. **44** for another illustrative embodiment.

FIG. **63** is similar to a portion of FIG. **53**B for another illustrative embodiment.

FIG. **64** is a simplified, partial, sectional view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **65** is a simplified, partial, elevational view of an illustrative embodiment of an assembly of several components in accordance with the invention.

FIG. **66** is a simplified elevational view of an illustrative embodiment of a portion of a structure like that shown in FIG. **65** in accordance with the invention.

FIGS. **67**, **68**A, and **68**B are each similar to FIG. **66** for other illustrative embodiments.

FIGS. **69**A and **69**B are each similar to FIG. **48** for another illustrative embodiment.

FIG. **70** is similar to FIG. **50** for another illustrative embodiment.

FIG. **71** is similar to FIG. **61** for another illustrative embodiment.

FIG. **72** is similar to FIG. **47** for another illustrative embodiment.

FIG. **73** is similar to FIG. **65** for another illustrative embodiment.

FIGS. **74**A-C are each similar to FIG. **65** for other illustrative embodiments.

FIG. **75** is similar to FIG. **62** for another illustrative embodiment.

FIG. **76**A is similar to FIG. **63** for another illustrative embodiment.

FIG. **76**B is similar to FIG. **76**A with another illustrative component shown.

FIGS. **77**A-G are simplified sectional views showing various illustrative embodiments of leaflet attachment to other components of valves in accordance with the invention.

FIGS. **78**A and **78**B are each similar to FIGS. like FIGS. **53**A-B for other illustrative embodiments.

DETAILED DESCRIPTION

As just one example of a context in which the present invention may be employed, thousands of high-risk patients with severe aortic stenosis go untreated each year because they are deemed inoperable for a heart valve replacement. In an attempt to treat these patients, collapsible prosthetic heart valves have been developed to be inserted within the stenotic leaflets of these patients via percutaneous and/or trans-apical means. However, known designs may not sufficiently address several aspects of an optimal valve design, such as: (1) long-term durability, (2) mitral valve impingement, (3) perivalvular leakage, etc. Leaflet attachment can be a key element when considering some of these issues. The designs disclosed herein provide these high-risk patients with superior valves by better addressing these and other issues.

FIGS. **1**A-B provide a general overview of an illustrative embodiment of a stent structure **10** that can be used in valves in accordance with this invention. These FIGS. show an expanded stent with independently flexing commissure posts **20***a-c* to reduce stress imparted to the valve leaflets (not shown). (Although this embodiment and several other embodiments have independently flexing commissure posts, still other embodiments are shown that also increase valve durability and that have only partially or not independently flexing commissure posts.) The independent posts are partly separate from the anchoring structure **30** downstream from the patient's valsalva sinus (upper portion of structure as viewed in FIGS. **1**A-B) and 40 adjacent the patient's native aortic valve annulus (lower portion of structure as viewed in FIGS. **1**A-B). In particular, upper free end portions of posts **20***a-c* are cantilevered from the annulus portion **40** of stent **10**. (Again, however, other embodiments may have only partially cantilevered or non-cantilevered commissure posts.)

FIGS. **2**A-B show an illustrative embodiment of an expanded and contoured stent **10** with skirt flare **50** on base **40** and an extra-expanded section **30** for the aorta. (Reference numbers are reused for generally similar features in different FIGS. and different embodiments. Some FIGS. do not show the rear or the complete rear of all structures to avoid over-complicating the depictions.) Attachment of leaflets (not shown) to posts **20***a-c* and covering of the stent are important aspects of this invention.

FIGS. **3**A-B show an illustrative embodiment of an expanded and contoured stent **10** with valve leaflets **60***a-c* and buffer layer **70** and outer cuff material **80**. Note that commissure posts **20** can lie perfectly vertically, or alternatively they can be angled inwardly to bias the leaflets inwardly and thereby help to keep them from hitting the prosthetic valve frame and/or the surrounding patient anatomy during opening.

Attachment steps (in any order) after a stent **10** is at a predetermined diameter and polished are generally the following:

- Flexible leaflets **60***a-c* (e.g., polymer sheet or pericardial tissue sheet) are processed and cut to shape.
  - For example, tissue leaflets **60***a-c* can be laid flat and fixed with the use of glutaraldehyde or triglycidylamine before being treated with an anti-calcification treatment such as at least a 60% solution of ethanol.
- Buffer material or materials **70** (e.g., polymer sheet or pericardial tissue sheet) are processed and cut to shape.
- Cuff material **80** (e.g., polyester fabric sheet) is formed into a tube of the appropriate diameter and cut to length.
- Cuff material **80** can cover the lower portion of stent **10**, the entire portion of where the leaflets are attached, and/or the entire stent including an aorta section.
- Intermediate materials of one or more layers (sheets) between stent **10** and leaflet material **60** may be applied for attachment, friction buffering, and tissue in-growth purposes. For example, an interface between two polymer or tissue layers may be beneficial, as compared to an unbuffered interface between leaflets **60** and stent **10**, for the above-mentioned reasons (e.g., less friction on and therefore wear of leaflets **60**). Lubricious polymer coating of the stent instead of just sheets may also be incorporated.
- Leaflets **60** are attached to stent **10** and around the circumference of the stent base.

Specific details as to how the valve is assembled for different types of stent posts **20** are given below.

FIG. **4**A shows the flat and collapsed state of a stent model used to laser-cut a part (stent) **10** from a tube (e.g., of a super-elastic metal such as nitinol or a balloon-expandable material such as cobalt chromium). FIG. **4**B shows a round laser-cut part (stent) **10** in the collapsed state. This stent embodiment has independent flexing commissure posts **20***a-c* that are solid except for one set of eyelets **22**. Note, however, that these eyelets can be converted to any orifice shape such as an elongated slot.

FIGS. **5**A-B show the flat and collapsed state of a stent model used to laser cut a part (stent) **10** from a tube and a close-up of the independent commissure posts **20***a-c*. This stent **10** has independent flexing posts **20***a-c* that are solid with two sets of eyelets **22**. However, these eyelets could be converted to any orifice shape such as elongated slots. Note the bend line **52** of the skirt **50** and the base line **54** of the stent discussed in connection with later FIGS.

FIG. **6** shows a buffering layer **70** that outlines the inner surface of a stent **10** (actually stent portion **40**) and posts **20***a-c* to ensure that there is no contact between the leaflets **60** and any other material. Each rectangular section **72** is sutured to the inner diameter of a respective one of posts **20**. Top lip **74** covers the inner portion of the stent cells above bend line **52** (see also FIG. **5**B). Bottom lip **76** covers the inner portion of the stent cells below bend line **52** to the bottom **54** of the stent (see also FIG. **5**B). If section **78** is present, it can be wrapped around the bottom edge **54** of the stent from the inner diameter to the outer diameter to be terminated at the bottom stent edge or farther up. Note that the triangular cut-outs **79** in this section allow for flexible movement of the edge and actually will meet when wrapped around the bottom edge, while the rounded extreme bottom edge sections **77** will meet to form one continuous circular path around the stent. The triangular cut-outs **79** also allow for a minimized chance of tearing during expansion and contraction of the valve.

FIG. **7** shows that the buffering layer **70** of this and all presented designs in this invention disclosure can be made from three single sections as shown in this FIG. (in contrast to one single piece as shown in FIG. **6**).

FIG. **8** shows additional features that can be included in buffering designs in accordance with the invention. (See FIG. **6** for general features that apply to all buffering designs of the invention.) Top flaps **71** wrap around the tops of the posts **20** from the inner diameter (ID) to the outer diameter (OD). Side flaps **73** wrap around the left and rights sides of each post **20** from the ID to the OD and are secured by sutures.

FIG. **9** shows that in areas of high complexity, individual buffering strips **70** of various sizes and shapes can be wrapped about the stent frame and sutured in place. FIG. **9** shows a generic rectangular strip **70** as an example. A rectangular strip can be rolled to form a cylinder of a desired height to cover any portion of the stent as well.

FIG. **10** shows a single leaflet design **60** that is the foundation for many of the following leaflet designs in this disclosure. Material **61** above the top-most horizontal dotted line is for redundant coaptation where all three leaflets **60***a-c* meet under back-pressure. (The various dotted lines are shown primarily for reference, although they can also actually appear on the leaflet (either temporarily or permanently) as a visual guide or aid for use during assembly of a valve.) Side flaps **62** bend at the angled lines and provide an area to suture to the commissure post **20** ID. Note that since the leaflet may be cut from a flat sheet, there may not be a belly-shaped contour in the leaflet body **63**; but when the angled side flaps **62** are attached to a vertical post **20**, this allows for the top portion of the leaflet to be closer to the central axis of the stent than the bottom portion, thus creating central coaptation. Side flaps **62** wrap around the left and right sides of the commissure posts **20** from the ID to the OD and are sutured down. Bottom flap **64** covers the ID portion of the stent cells below the bend line **52** to the bottom **54** of the stent. If this section is present, it can be wrapped around the bottom edge **54** of the stent from the inner diameter to the outer diameter to be terminated at the bottom stent edge or farther up, depending on its length. Note that the triangular cut-out **65** in this section allows for flexible movement of the edge and actually will meet when wrapped, while the rounded lower edge sections **66** will meet to form one continuous circular path around the stent. If desired, the material along curve **67** can be sutured down to form a natural belly shape for the leaflet. The bottom side flap **68** allows for some overlapping of adjacent leaflets to ensure that the inflow skirt edge is fully sealed. Triangular cut-outs **65** also allow for a minimized chance of tearing during expansion and contraction of the valve.

FIG. **11** shows three single leaflets **60***a-c* being attached to stent **10**. The bottom flaps **64** and side flaps **62** can easily be seen before attachment occurs.

FIGS. **12**A-C show three illustrative methods for leaflet and ancillary component assembly. Each of these FIGS. shows a top view of a commissure post **20** on the stent. (The commissure post is the large rectangle **20** in each of these FIGS.) In FIGS. **12**A and **12**C the commissure post has a single set of orifices **22**. In FIG. **12**B the commissure post has two sets of orifices **22***a* and **22***b*. In FIGS. **12**A and **12**B a buffering layer **70** is only on the ID surface of the post (which is the upper surface as viewed in these FIGS.). In FIG. **12**C buffering layer **70** is wrapped all the way around the post. Lines **60***a* and **60***b* illustrate representative leaflets, and the arrows at the top ends indicate that the leaflet material continues beyond what is seen in the FIG. toward the central axis of the valve. The dotted lines **90** indicate a suture passing through the eyelet(s) **22** and through the leaflets **60**. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **60** reduces abrasion, (2) leaflets **60** are sutured together to minimize any post gapping, (3) suture knots are on the OD of the post so as not to interfere with leaflet movement/abrasion, and (4) free ends **62** of the leaflets are curled back (e.g., toward the center of the valve) to provide an additional buffering layer. Note that in FIG. **12**C the leaflets can only be wrapped around the post from the ID to the OD (as at **62**) if there is enough room between stent cells when the valve is collapsed.

FIG. **13** shows that on the fabric covering **80** on the ID of the stent there is a thin buffering material **70** to protect the leaflets **60** from abrading against the other valve surfaces. The lack of post gapping and the curled back leaflet edge before it is trimmed can be seen here at **100** (see also FIG. **12**A).

FIG. **14** shows how angled side flaps (**62** of FIG. **10**) allow leaflets **60***a-c* to coapt along the central axis **110**. Note that under blood flow back-pressure, the leaflets will close tightly together with redundant coaptation.

FIGS. **15**A-B show two different valve variations that have a few key differences. FIG. **15**A has a cuff and buffer section **70/80** that covers all of the expanding cells of stent portion **40**. In FIG. **15**B structure **70/80** goes half of the way up the stent cells **40** to approximately the bend line **52**, which may leave metal exposed for leaflet contact during opening. FIG. **15**A has a buffering layer and leaflets that terminate at the lower edge **54** of the stent, whereas the buffering layer and leaflets of FIG. **15**B completely wrap over the bottom edge **54** and are anchored near bend line **52**. Any or all of these features can be combined.

FIG. **16** shows that there is a complete seal from the leaflets **60** and buffering layer all of the way from the stent ID around the edge of the stent base skirt to allow for a complete seal.

FIG. **17** shows that to allow for more transfer of leaflet load to the stent posts **20** (as opposed to almost entirely through point loads from the sutures **90** on the stent ID), sutures and/or leaflet material may need to be passed over the top of the post **20** and secured to the OD as indicated at **120**.

FIGS. **18**A-B show that to allow for more transfer of leaflet load (high-stress region **130** near leaflet free edge) to the stent post **20** (as opposed to almost entirely through point loads from the sutures **90**), individual leaflets **60***a-c* can be secured to caps **140** placed over the post tops. Caps **140** can be made from fabric, polymer, and/or tissue components.

FIG. **19** shows another single leaflet design in which many of the same features as described in FIG. **10** can be utilized. The primary difference in this design is that the edge **62/64** is curled back onto the OD of the leaflet along the illustrated indicator lines **67/69**, instead of folded around the base of the stent. So instead of the leaflet edge sealing for inflow of the stent skirt, this design forms a pocket under back-pressure, with no seams along the suture line. For a 3D illustration see the next FIGS. As with the previous design, when these flaps are folded back, the triangular sections **65** close so the leaflet does not buckle. Since these flaps are folded back up against the leaflet OD, when the leaflet opens, the flaps **64** actually form a buffer between the upper base stent portion **40** and the leaflet.

FIGS. **20**A-B shows 3D views of single leaflets **60**. FIG. **20**A is a top view cross section, and FIG. **20**B is a side view cross section. The arrows indicate where the leaflet flaps **62/64** are folded back onto the leaflet OD for one representative leaflet **60***b*. Note that the curled-back design illustrated in FIGS. **12**A-B is similar, except that in this design it runs along the entire edge **67/69** instead of just along the post.

FIG. **21** shows a flat cutout of a continuous leaflet **160**. Instead of three single leaflets **60***a-c* mating together to form an orifice **150**, this design achieves this with one single continuous piece **160** of leaflet material. The indicated edge **170** is sewn to the stent ID in a similar manner as already described. Dashed line **180** indicates where leaflet material **160** is creased to form a commissure and attached to a post **20**. When the flat portion **190** of this design is pushed toward the central axis, it forms a belly as shown in the next FIG.

FIG. **22** shows a folded 3D illustration of continuous leaflets material **160**. See the above discussion of FIG. **21** for item descriptions.

FIGS. **23**A-B show two methods for leaflet **160** and ancillary component assembly. These are views similar to FIGS. **12**A and **12**C, with the same reference numbers used again for similar components. Major features to note are as follows: (1) a buffering layer **70** between the stent **20** and the leaflet material **160** reduces abrasion, (2) leaflets **60** (from continuous leaflet structure **160**) are sutured together to minimize any post gapping, (3) suture knots are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, and (4) bottom edge of the leaflets are curled back up toward the center of the valve to allow for an additional buffering layer (analogous to the folding along line **67** in FIGS. **20**A and

20B). Note that the main difference in attachment techniques is that either the leaflet material **160** wraps around the entire stent post (FIG. **23**A) if there is enough room between cells when the valve is collapsed, or the leaflet material **160** is folded on the post ID only (FIG. **23**B) in a continuous manner.

FIGS. **24**A-B show the flat and collapsed state of a stent model used to laser cut a part (stent **10**) from a tube and a close-up of the independent posts **20**. This stent has independent flexing posts **20** that are solid, with two sets of eyelets **22**, and an open section **24** at the top that forks (bifurcates) into two separate portions. See FIGS. **1-5** for general features that are applicable to this and other designs.

A buffering layer **70** that can outline the ID of this stent **10** can be seen in FIGS. **6-8**, but would have a fork-shaped top.

FIGS. **25**A-B show single leaflet designs (with many of the same features as conveyed in FIGS. **10** and **19**) that can be used for this stent design. The main difference is that the side flaps **62** have a slit **200** in them that allows the flap to wrap around the OD of the fork (on both sides of open section **24**) at the top of the stent post **20**.

FIGS. **26**A-B show two methods for leaflet **60** and ancillary component assembly. Once again, these are views that are similar to FIGS. like **12** and **23**, with the same reference numbers being used again for similar components. Major features to note are as follows: (1) a buffering layer **70** between stent **10** and leaflets **60** reduces abrasion, (2) leaflets **60** are sutured together (using sutures **90**) to minimize any post gapping, (3) suture knots are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, (4) free ends **62** of leaflets **60** are curled back toward the center of the valve to provide an additional buffering layer in FIG. **26**A, (5) the gap **24** between forked posts **20** is just large enough for leaflet thicknesses to eliminate post gapping, and (6) the leaflets attached to the OD as in FIG. **26**B allow for stresses caused from blood flow back-pressure to be transferred to the stent frame **10** instead of point loads at suture attachments.

FIG. **27** shows a 3D view of individual leaflets **60** and the top portion **202** of the side flaps (above slit **200** in FIG. **25**A or **25**B) that wrap around the forked top section of the stent post **20**.

FIG. **28** shows that another variation of this stent design is to eliminate the eyelets **22** on the lower portion of posts **20**. If there are no orifices to attach the leaflet flaps **62** to the posts, the leaflet flaps can be sutured together along the length of this lower section and/or through cuff material surrounding the expandable stent portion.

FIGS. **29**A-B show the flat and collapsed state of a stent model used to laser cut a part (stent **10**) from a tube and a close-up of the independent posts **20**. This stent has independent flexing posts **20** that are open in the middle **24** (i.e., bifurcated) with two sets of eyelets **22**. It also has a terminating single eyelet **26** for anchoring the leaflet base and other materials. See again FIGS. **1-5** for general features that are applicable to this and other designs.

FIG. **30** shows an example of a design variation with the non-expanding open stent post **20** and flared skirt **50**.

FIG. **31** shows a close-up of the flat and collapsed state of a stent model used to laser cut a part (stent **10**) from a tube with independent commissure posts **20**. This stent has independent flexing posts **20** that are open in the middle (i.e., at **24**), with two sets of eyelets **22**. Additionally, this design has a connection **28** higher up on the stent posts **20**, thus making the posts less cantilevered and therefore possibly less flexible if needed. However, the valve assembly is not disrupted when internally mounting the leaflets through the center slot **24** of the stent posts. See again FIGS. **1-5** and **29** for general features that are applicable to this and other designs.

FIG. **32** shows a buffering layer design including features that can be in addition to those shown in FIG. **6**. Rectangular flaps **72** outline the ID of stent posts **20**. An "I" shaped slit **210** is cut through material **70** and the resulting flaps are wrapped through the middle portion **24** of the stent post **20** from the ID to the OD, then secured in place.

FIGS. **33**A-B show single leaflet designs, with many of the same features as conveyed in FIGS. **10** and **19**, which can be applied to this stent design. The main difference is that the entire side flaps **62** pass through the middle slot (**24** of FIG. **29**) and around to the OD, where it is secured (see next FIG.).

FIG. **34** shows one method for leaflet and ancillary component assembly. Once again, this is a view similar to FIGS. like **12** and **23**, with the same reference numbers being used again for similar elements. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **60** reduces abrasion, (2) the gap **24** between sides of the post **20** is just large enough for leaflet thicknesses to eliminate post gapping, (3) suture knots (associated with sutures **90**) are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, and (4) the leaflets **60** attached to the OD of posts **20** allow for stresses caused by blood-flow back-pressure to be transferred to the stent frame instead of point loads at suture attachments.

FIGS. **35**A-B show an example of this type of design with single leaflets **60** pulled through a center slot **24** and wrapped around to the OD of the stent post **20**. Also note that the buffering material **70** and leaflets **60** wrap slightly around the stent base as indicated at **220**. In some areas these FIGS. show the leaflet material as though transparent.

FIG. **36** shows a flat cutout of a continuous leaflet **160**. Instead of three single leaflets **60** mating together to form an orifice **150**, this design achieves this with one single continuous piece **160**. The indicated edge **170** is sewn to the stent ID in a similar manner as already described. Dashed lines **180** indicate where one representative commissure of the leaflets is creased and pulled through the central slot **24** of the post **20**. When the flat portion **190** of this design is pushed toward the central axis, it forms a belly as shown in previous FIGS.

FIG. **37** shows one method for leaflet and ancillary component assembly. Again, FIG. **37** is a view similar to FIGS. like **12** and **23**, and the same reference numbers are used in all FIGS. of this type to indicate similar components. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **160** reduces abrasion, (2) the gap **24** between sides of the post **20** is just large enough for leaflet thicknesses to eliminate post gapping, (3) suture knots (associated with sutures **90**) are on the OD of the post **20** so as not to interfere with leaflet **160** movement/abrasion, (4) the leaflets **160** attached to the OD (at **180**) allow for stresses caused from back-pressure to be transferred to the stent frame **10** instead of point loads at suture attachments, and (5) the leaflet **160** is fully sealed at the commissures **20**.

FIGS. **38**A-B show the flat and collapsed state of a stent model used to laser cut a part (stent **10**) from a tube and a close-up of the independent commissure posts **20**. This stent has independent flexing posts **20** that are open in the middle **24** with two sets of eyelets **22**. Additionally, this design has an opening **28** at the bottom of the slot **24**, which allows the post **20** to expand into a triangular shape. See again FIGS. **1-5** for general features that are applicable to this and other designs.

FIG. **39** shows an example of a stent variation with a central vertical slot **24** when in a collapsed state that was formed into a triangular opening **24**/**28** in an expanded state. The triangular opening of this post **20** more closely mimics the contoured shape of a native valve than, say, a vertical non-expanding post.

FIG. **40** shows a buffering layer design including features that can be in addition to those shown in FIG. **6**. The upwardly extending post flaps **72** outline the ID of stent posts **20** when those posts are expanded into a triangular shape (e.g., as shown at **24/28** in FIG. **39**). A slit **210** is cut through buffering material **70** and the resulting flaps are wrapped through the middle portion **24/28** of the stent posts **20** from the ID to the OD, then secured in place.

FIGS. **41**A-B show single leaflet designs, with many of the same features as conveyed in FIGS. **10** and **19**, which can be applied to this stent design. The main difference is that the side flaps **62** at the commissures are spread apart (due to the triangular stent post opening **24/28**), thus additional sealing measures are needed.

FIG. **42** shows one method for leaflet and ancillary component assembly. This is yet another FIG. similar to FIGS. like **12** and **23**, and which uses the same reference numbers for similar elements. In addition, line **230** indicates a patch having the same or similar material properties as elements **70** or **60** that seals the triangular opening **24/28** in the posts **20**. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **60** reduces abrasion, (2) suture knots (associated with sutures **90**) are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, (3) the leaflets **60** attached to the OD via flaps **62** allow for stresses caused from back-pressure to be transferred to the stent frame **10** instead of point loads at suture attachments **90**, and (4) the triangular-shaped posts **20/24/28** more closely mimic the contour shape of a native valve, thus functioning more optimally.

FIG. **43** shows an example of a stent variation with an open expanding post **20** that results in a triangular commissure area **24/28** that more closely mimics the contour shape of a native valve. A patch **230** is sutured through the eyelets **22** and around the base of the stent **10** to ensure a sealed environment. Note also that there is a double layer of cuff material **80** on the stent OD to aid in better sealing and tissue in-growth when pushed against native aortic root tissue.

FIG. **44** shows a single leaflet design, with many of the same features as conveyed in FIG. **10**, which can be applied to this stent design. The main difference is that one side flap **62** has an extension **162** that is used to seal the triangular-shaped opening.

FIG. **45** shows one method for leaflet and ancillary component assembly. This is again similar to FIG. **42**, and the same reference numbers are used for similar elements in both of these FIGS. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **60** reduces abrasion, (2) suture knots are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, (3) the gap **24** is large enough for leaflet thicknesses to eliminate post gapping, (4) the leaflets **60** attached to the OD of post **20** allow for stresses caused from blood flow back-pressure to be transferred to the stent frame **10** instead of point loads at suture attachments **90**, and (5) the doubling back of the one leaflet at **162** aids in sealing the triangular stent post opening **24/28**.

FIG. **46** shows an example of a single leaflet design with an enlarged triangular side flap **162** that is doubled back over itself to aid in sealing the triangular expanded post opening **24/28**. FIG. **46** omits depiction of the sutures that are typically used to secure the leaflet and flap material to the stent frame.

FIG. **47** shows a flat cutout of a continuous leaflet **160** with several features that aid in the attachment and sealing for an expanding post **20/24/28** design. Flaps **240** with triangular cutouts **242** are wrapped around the base of the stent **10**. Edge **250** is sutured to the stent **10** to form the base of the leaflet belly. Edge **244** is secured around the base of the stent **10**. Sections **260** are pulled through the triangular post opening **24/28**, folded around the OD of the post **20**, and doubled back on themselves. Sections **262** cover up the triangular openings **24/28**. Flaps **270** extend toward the base of the stent to enhance sealing of covers **262** and are joined to the other flaps **240** along their edges **246** and **276**. See the next FIG. for more detail.

FIG. **48** shows one method for leaflet and ancillary component assembly. This is again similar to FIG. **45**, and again uses the same reference numbers for similar elements. Major features to note are as follows: (1) a buffering layer **70** between the stent **10** and the leaflets **160** reduces abrasion, (2) the gap **24** between sides of the posts **20** at the upper apex of the triangular stent post opening is just large enough for leaflet thicknesses to eliminate post gapping at that location, (3) suture knots are on the OD of the post **20** so as not to interfere with leaflet movement/abrasion, (4) the leaflets **160** attached to the OD of post **20** allow for stresses caused from blood flow back-pressure to be transferred to the stent frame **10** instead of point loads at suture attachments **90**, and (5) the leaflets **160** are fully sealed at the triangular commissures **20/24/28** as indicated at **262**.

FIG. **49** shows an example of a single leaflet design doubled over itself at the edges **260** with a triangular section **262** in the middle to achieve a continuous tight seal.

FIG. **50** shows further development of structures like those shown in FIGS. **5**A and **5**B. FIG. **50** shows a combination of eyelets **22** and slots **23** (already mentioned as a possibility earlier in this specification). The top and bottom post eyelets **22** anchor the leaflets **60** into position, and the slots **23** allow for easier assembly and multiple passes of a stitching needle. FIG. **50** shows the metal structure **10** in a flat or planar depiction and in its collapsed condition or configuration. Again, there is a combination of eyelets **22** and slots **23** on the commissure posts **20** for leaflet **60** attachment. Eyelets **21** in other areas can be variously used to attach leaflets **60**, cuff material **80**, and/or buffering material **70**. FIG. **51** shows the FIG. **50** structure in its expanded state.

FIG. **52** shows an illustrative simplification of a single leaflet design of the general type that is shown in FIGS. **10** and **19**. This simplified version allows the technician to assemble and trim the valve as needed, since there can be a variability in how the tissue behaves. This design also reduces the amount of openings to enhance sealing. The same principles apply as are discussed above in connection with FIGS. **10** and **19**. Note also that this design can be used for FIGS. **10** and **19** valves, and then trimmed to the shape of the stent **10** if needed.

FIGS. **53**A and **53**B show further development of structures of the type that are shown in FIGS. **12**A-C. In particular, FIGS. **53**A and **53**B show the front (outer diameter) view of a straight solid commissure post **20** and suture attachment **90***a* and/or **90***b* for leaflets **60**. Note that these basic concepts can be used on the other post designs. FIG. **53**A shows sutures **90***a* only looped around the stent material in the vertical direction. FIG. **53**B shows sutures **90***a* in the vertical direction and sutures **90***b* in the horizontal direction, which is more indicative of what is shown in the top views of FIGS. **12**A-C.

FIGS. **54-57** show further development of structures of the general type shown in FIGS. **13-16**. FIGS. **54-57** are examples of modified stents **10** with tissue structures added. FIG. **54** is a side view of a valve with tissue leaflet **60** attachment like FIG. **53**A. FIG. **55** is a top view similar to FIG. **13**, but with tissue leaflets **60**. FIG. **56** is a bottom view with leaflet tissue wrapped around the bottom edge. (This leaflet tissue may also be over other layers of fabric and/or buffer material, depending on the design of the valve.) FIG. **57** is a bottom view with tissue terminated at the bottom edge. Note also that the traces **300** for the leaflet shape are shown. These traces **300** can be temporary (or permanent) markings on the leaflet material to help the assembly technician properly shape and assemble the valve.

FIGS. **58**-**60** show further development of structures like those shown in FIG. **20**. FIGS. **58**-**60** show valves built with this concept to further clarify how the valve actually looks. FIG. **58** is a bottom view of leaflets folded to form pockets when the free edges of the leaflets are coapting. FIG. **59** is a top view showing continuous pockets **310**. FIG. **60** is a side view showing continuous pockets **310** and the rolled up leaflets trimmed to the outline of the stent at **320**. Buffer and cuff material can also be shaped to outline the contour of the expandable stent portion.

FIG. **61** shows further development of structures like those shown in FIGS. **30** and **31**. FIG. **61** shows a further developed version of a nitinol part (stent) **10** that has been expanded. This design also incorporates eyelets **22** and slots **23**, as well as eyelets **21** in various locations around the stent for attachment. Note that this design also has an extra row of closed-perimeter, open-centered, circumferentially collapsible/expandable cells on the bottom section **40**/**50** as compared to the earlier examples.

FIG. **62** shows a single leaflet shape **60** which may have several advantages. For example, as compared to some leaflet shapes described earlier in this specification, the FIG. **62** shape can reduce the amount of leaflet tissue that needs to be collapsed when the prosthetic valve is collapsed. This can help the prosthetic valve collapse to a smaller size for less invasive delivery into a patient. This leaflet shape can also help to redistribute high stress areas in the base of the valve belly where tear-out might otherwise tend to occur. All of these modifications can improve valve function and durability.

As in some earlier-described embodiments, lines **300** are indicator lines on leaflet **60** to help with assembly of the leaflet into a prosthetic valve. In addition, some of these lines serve to demarcate certain portions of the leaflet in the following discussion. Line **300***a*-*b* is a line along which leaflet material outside the line can be folded in on leaflet material inside the line. Especially line **300***b* is also a line along which the base of the leaflet may be sutured to other structure of the valve. For example, this may result in securing the base of the leaflet through cuff material **80** of the valve. This arrangement helps to distribute stresses at the base of the leaflet (e.g., in the area indicated generally by reference number **400**) upwardly along curve **300***b* (e.g., into the areas indicated generally by reference number **410**) to spread out these stresses and prevent them from concentrating right at the leaflet base. For example, FIG. **64** shows how leaflet material **62***b* outside indicator line **300***b* may be folded up outside the remainder of a leaflet **60**. This produces a doubled-over layer of leaflet material, which can be sutured through (including to other structure of the valve) using sutures **90** to improve durability.

Returning to FIG. **62**, and also now referring to a representative prosthetic valve commissure post **20** as shown in FIG. **63** for use with the FIG. **62** leaflet, leaflet flap portion **62***a* may be positioned relative to post **20** so that portion **62***a* sits above the top-most horizontal eyelet **23***a* in post **20**. Leaflet flap portion **62***c* is then positioned between horizontal eyelet **23***a* and the top-most vertical eyelet **23***d* in post **20**. Below flap section **62***c* is a further leaflet flap section **62***d*, which is positioned for attachment (e.g., via sutures) to three vertical eyelets **23***d* in the upper portion of stent post **20**. Dotted line **420** in FIG. **63** indicates the approximate boundary of leaflet flap portion **62***d* when thus secured to post **20**. The area of post **20** below eyelets **23***d* can be used as additional area for, e.g., cuff **80** attachment, hiding suture knots, and other features.

As compared to some earlier-described leaflet embodiments, the FIG. **62** leaflet can include less leaflet material outside indicator line **300***b*. As noted earlier, this can help reduce the amount of leaflet material in the valve and thereby facilitate collapsing the valve to a smaller circumferential size.

Turning now to another consideration that may be important in construction of prosthetic heart valves in accordance with the invention, when a leaflet **60** is secured through cuff material **80**, it may be desirable to ensure a durable securement of the leaflet with reduced movement that could lead to cuff/suture/leaflet abrasion. Termination of a cuff **80** (especially when the stent is flared outward as at **50** in some embodiments herein) can be difficult. FIG. **65** and several subsequent FIGS. show structures that can help to address these issues.

As shown in FIG. **65**, cuff **80** is secured by outlining the struts of the cells that form stent portions **40** and **50** with whip stitch sutures **90***a*. In addition, stent portions **40** and **50** are constructed so that they include several annularly extending serpentine, undulating, or zig-zag members **42***a*-*c* that are connected to one another by vertical bars **44**. Serpentine members **42***a*-*c* annularly compress or expand to allow the prosthetic valve to circumferentially collapse or expand. But vertical members **44** do not change length during such annular compression or expansion of the serpentine members. This helps to reduce the amount by which the prosthetic valve changes axial length during circumferential compression or expansion. This in turn can help reduce any tendency of cuff **80** to shift relative to stent portion **40**/**50**. Vertical bars **44** can also be secured to cuff **80** by suture stitches **90***b*. In this example, cuff **80** and buffer material (hidden between the fabric of cuff **80** and leaflets **60**) are mounted in the inside diameter ("ID") of the stent and can extend any distance up or down the height of the stent frame. (Although FIG. **65** shows all of components **20**, **42**, and **44** one-piece with one another, some or all of these components may initially be separate from one another and then assembled with the other components.)

In addition to the above, the invention can address possible difficulty in firmly securing cuff **80** to stent cell ends. For example, especially when stent portion **40** is flared as at **50**, the adjacent cuff material **80** may have a tendency to slip vertically along the stent when a leaflet **60** is secured to the cuff material and under load. Reference number **440** in FIG. **65** points to a representative location where this may be an issue. Passing a suture through an eyelet **91** at such a location **440** can help prevent material slip. FIGS. **66**-**68** also show several others shapes that can be provided at the top and/or bottom of stent cells to help secure the cuff **80** to the stent more securely. For example, FIG. **66** shows providing an enlarged knob **450** on the end of a representative stent cell **40**/**50**. Knob **450** is connected to the stent cell by a small neck region **452**. Suture material **90** can be wound around neck **452** as shown in FIG. **66** to help prevent any other material that is secured to the stent by suture **90** from moving upwardly (in this example) away from the depicted stent cell end.

As another example, FIG. **67** shows a notch **460** in the stent material, which notch opens away from the associated stent cell end **40**/**50**. Suture material **90** can pass (repeatedly) from the stent cell end through notch **460** and back into the stent cell end to ensure that the suture (and anything secured by the suture) cannot shift upwardly (in this example) relative to the stent cell end.

As still another example, FIG. **68**A shows a partially formed eyelet **470** at the end of a stent cell **40/50**. Eyelet **470** is large enough for suture material **90** to pass through, but it may not be large enough for the suture needle to pass through. However, suture material **90** can be pulled into eyelet **470** through the open side **472** of the eyelet (which open side faces away from the apex or end of stent cell **40/50**). Suture material **90** may pass (repeatedly) from inside stent cell **40/50** through eyelet **470** and back into stent cell **40/50** in a loop, FIG. **8**, or other pattern to secure suture **90** and any other material (such as cuff **80**) that is engaged by suture **90** to the end of the stent cell. Again, as in the case of the structures shown in FIGS. **66** and **67**, this is done in such a way that other material (such as cuff **80**) that is secured by suture **90** cannot move upwardly (in this example) relative to the end of stent cell **40/50**.

FIG. **68**B shows an alternative to FIG. **67** in which the suturing **90** is interlocked with itself as part of passing through notch **460**. The interlocking shown in FIG. **68**B can also be used with other stent frame shapes such as the shape shown in FIG. **68**A.

FIG. **69**A shows a possible modification of a structure like that shown in FIG. **12**B. In this alternative a reinforced core **500***a* or **500***b* lines the creased area that the flaps of leaflets **60***a* and **60***b* are folded around. The core material **500***a/b* can be other tissue, polymer, metal, and/or fabric. The flap of the leaflet **60***a* or **60***b* is sutured (**90***a* or **90***b*) through the stent **20** in a manner similar to what has already been shown. The flaps of the leaflets **60***a* and **60***b* can be additionally wrapped around the core(s) **500***a/b* and secured via additional suturing **510** to form a bundle. This may add more reinforcement from tissue tears and may also mitigate leaflet abrasion as illustrated by FIG. **69**B. By binding the leaflet (e.g., **60***b*) and core (e.g., **500***b*), the leaflet is not allowed to open all of the way up to hit the frame **10** of the stent. In other words, a clearance like that indicated by double-headed arrow **520** in FIG. **69**B is maintained.

FIG. **70** shows an example of a self-expanding stent design with the downstream-most connections **530** between commissure posts **20** and the remainder of annulus portion **40** more than 50% up the post height in the direction of blood flow through the implanted valve. This means that in this embodiment the posts **20** are less cantilevered than in some other embodiments. This design still retains the ability to attach the leaflets to other structure of the valve in ways similar to what has been described for other embodiments.

FIG. **71** shows an example of a balloon-expandable stent design with the downstream-most connections **530** between each stent post **20** and the remainder of the stent **10/40** all the way up to the top of the posts **20**. FIG. **71** shows stent **10** in its fully expanded state. This design still retains the ability to attach the leaflets of the prosthetic valve to other structure of the valve in ways that are similar to what is shown and described for other embodiments. The FIG. **71** stent includes attachment structures **470/472** at the base of the stent that are similar to what is shown in FIG. **68**. These can also be used as interlocks for attachment of the prosthetic valve to a delivery system for that valve.

FIG. **72** shows another example of one continuous sheet **160** of leaflet material that can be shaped (when attached to a valve stent, etc.) to provide all three leaflets of a valve. FIG. **72** thus shows an alternative to what is shown in other FIGS. like FIG. **21**. This continuous design has flaps **540** built in to attach to the tops of the commissure posts **20** as described elsewhere in this specification. Another difference is radially inward contour or bulge of the free edge **61** of what will be each leaflet. This bulge gives the leaflets additional coaptation when the valve is closed.

FIG. **73** illustrates the point that several of the principles of this invention can be applied to collapsible and re-expandable prosthetic valves that use leaflets that are not just from sheet material. For example, a bovine jugular or porcine aortic root (or individual leaflets) **550** can be attached to the commissure posts **20** of a valve stent. In other words, in the prosthetic valve shown in FIG. **73**, the valving action is provided by the inclusion of an intact tissue valve (or leaflet cusps) **550** taken from an animal.

FIGS. **74**A-C show several illustrative variations on what is shown in FIG. **65**. For example, in FIG. **74**A reference line **560***a* indicates the contour of one representative leaflet where it is attached (near its bottom or upstream portion) to the cuff **80** of the valve. (Apart from reference line **560***a*, FIG. **74**A omits leaflets **60** and does not attempt to show the rear of the structure. Reference line **560***a* is shown primarily for purposes of explanation. This line does not itself depict structure, but rather is primarily just for geometric reference. The same is true for reference lines **560***b* and **560***c* in later FIGS.) FIG. **74**A may show a balloon-expandable valve with a fabric cuff **80** and a porcine tissue buffer layer (hidden on the inside diameter ("ID") of fabric **80**) attached to about 75% of the height of the annulus portion **40** of the stent (i.e., the lower 75% of the annulus portion **40** height). (Stent portion **40** may be called the annulus portion because it is typically implanted in or near the annulus of the patient's native heart valve annulus.) Reference line **560***a* in FIG. **74**A shows the lower portion of the leaflet attached straight across from the bottom eyelet **22** of one commissure post **20** to the next commissure post **20**. See also FIG. **75**, which shows an example of such a leaflet **60** with reference line **560***a* superimposed on it.

FIG. **74**B may show a self-expanding valve with the fabric cuff **80** and porcine tissue buffer (hidden on ID of the fabric) attached to the full height of the annulus portion **40** of the stent. As indicated by the reference line **560***b*, a typical leaflet **60** is attached part of the way up the posts **20**, and the belly section of the leaflet gradually contours (curves) toward the stent base below the posts (see also FIGS. **76**A-B, which are discussed below).

FIG. **74**C may show a self-expanding valve with the fabric cuff **80** on the outside diameter ("OD") of the stent and porcine tissue buffer (not visible) on the ID of the stent. (Note that FIG. **74**C shows cuff **80** as though transparent, and that this FIG. omits depiction of the sutures that are typically used to secure cuff **80** to the stent frame.) As shown by the reference line **560***c*, a typical leaflet **60** in this case is attached near the bottom of the posts **20**, and the leaflet belly section gradually contours toward the stent base, at which point it can be attached to the base of the stent, cuff **80**, and features like those shown in FIGS. **66-68**.

FIGS. **76**A-B show an illustrative variation of a commissure post **20** (e.g., as in FIG. **63**) and the matching leaflet **60** (e.g., as in FIG. **74**B). From FIGS. **76**A-B it can be seen how the leaflet **60** matches up with various features of the stent post **20** as described earlier (e.g., in connection with FIG. **74**B). Note that the two bottom eyelets **23***e* are not needed for leaflet attachment, but are present for cuff **80** securement. Also, the pair of eyelets **23***d'* are placed slightly farther apart than the eyelet pairs above to aid in the transition of the leaflet contour (curve).

FIGS. **77**A-G illustrate several ways that leaflets can be assembled to other components of the valve. Whereas FIGS. like **69**A-B focus on the area of leaflet attachment to commissure posts **20**, FIGS. like **77**A-G can apply to leaflet attachment elsewhere than at commissure posts **20**. In each of these FIGS. the double vertical lines represent any desired arrangement and/or combination of elements like stent **10** (e.g., annulus portion **40**), buffer layer **70**, and/or cuff layer **80**. Element **60** is leaflet material, element **90** is suture material, and element **500** is a reinforcing core (e.g., as in FIGS. **69**A-B). The bottom portion **570** of a leaflet **570** can be folded and/or supported with core material **500** to create a stronger seam. This seam can then be secured to the cuff **80** and/or stent **10/40** via suture **90** using a variety of techniques. For example, the stitch **90** shown in FIG. **77**A pierces through the layers of leaflet tissue **60/570** once and whips around the bottom. The stitch shown in FIG. **77**B pierces through the layers of tissue **60/570** twice. A reinforced core **500** (FIGS. **77**C-F) can be placed inside the folded leaflet **60/570**. The leaflet (main portion **60**) can be folded between the cuff **80** and the core **500** as shown in FIG. **77**C. Alternatively, the main portion of the leaflet **60** can pass in front of the core **500** as shown in FIG. **77**D. With the addition of a core **500**, the leaflet **60** may not need to be folded at all, but may simply be attached to the front/back of the core as shown in FIGS. **77**E and **77**F, respectively. Yet another option is to use a foldable core material **580**, by which to sandwich the end of the leaflet **60** as shown in FIG. **77**G. As noted earlier (e.g., in connection with FIGS. **69**A-B), the material of a reinforcing core can be other tissue, polymer, metal and/or fabric. Thus a reinforcing core like **500** or **570** can be rigid (e.g., metal or the like) or soft (e.g., fabric, tissue, or the like). The reinforcement can run along dotted suture lines shown on the leaflets in some of the FIGS. herein (e.g., line **575** in FIG. **76**B) or any portion of such a suture line. Rigid reinforcement members may have eyelets parallel and/or perpendicular to post **20** eyelets.

FIGS. **78**A and **78**B show some examples of suture patterns that may be used to attach leaflet flaps to commissure posts **20**. In FIG. **78**A one suture **90** is used to attach a leaflet flap to a post **20**. Beginning at the bottom right eyelet, the suture **90** is temporarily anchored at or near **590** where a suture tail remains. Suture **90** then runs from the bottom eyelet **23** to the top (back and forth through successive eyelets and a leaflet flap (not shown)) and then returns back down the same side (again back and forth through successive eyelets and the above-mentioned leaflet flap). Suture **90** then crosses over near **590** to the other column of eyelets to repeat the same pattern. Ultimately the suture end is tied off to the suture tail at **590**.

In the alternative shown in FIG. **78**B, each side of the post eyelets (i.e., the left side eyelets or the right side eyelets) are sutured independently (suture **90***a* starting from **590***a* on the left, and suture **90***b* starting from **590***b* on the right), and each suture is ultimately tied off to its own tail at **590***a* or **590***b*, respectively.

To some extent the appended claim terminology may differ from terminology used up to this point in this detailed description. Some specific examples of what certain claim terms refer to are as follows. Supporting structure **10**; sheet-like, flexible, leaflet member **60/160**; free edge portion of a leaflet **61**; flexible chord across an interior of the supporting structure (see, for example, reference number **131** in FIG. **18**A or FIG. **20**A; such a chord is typically not a straight chord, but rather a loose and flexible chord); material of the leaflet beyond an end of the chord forming a flap **62**; cylindrical surface defined by one of the inner and outer surfaces of the supporting structure (such cylindrical surfaces are abstract geometric shapes defined by what are earlier referred to, respectively, as the ID (inside diameter) and OD (outside diameter) of supporting structure **10**; these cylindrical surfaces are not necessarily round, but may instead have other shapes such as oval, elliptical, etc.); suture **90**; inner surface of the supporting structure (ID of supporting structure **10**); outer surface of the supporting structure (OD of supporting structure **10**); secured line portion(s) **67/170/250/300***b*; belly portion of the leaflet **63/190/310**; additional material of the leaflet beyond the secured line portion away from the belly portion forming a second flap **64/240/270/62***b*; axial end of the supporting structure, e.g., lower end of structure **10** as viewed in FIG. **1***a*; sheet-like, flexible, buffer material **70**; annularly spaced commissure posts **20***a-c*; cantilevered from other structure of the supporting structure, e.g., commissure posts **20** may have upper free end portions and are only attached to the remainder of supporting structure **10** below those upper free end portions (this cantilevering of the upper free end portions of the commissure posts gives the commissure posts what is sometimes referred to herein as independent flexibility, which means, for example, that the upper free end portion of a commissure post can flex radially inwardly and outwardly at least somewhat independently of other portions of supporting structure **10**) (note that in FIG. **65** the posts **20** are not cantilevered, but the entire stent frame flexes to reduce stress); commissure post bifurcated into two spaced apart members, e.g., the commissure post portions on opposite sides of notch or opening **24**; annular, annularly collapsible and re-expandable substructures **42***a-c* that are spaced from one another along an axis about which the supporting structure is annular; linking members **44** that are substantially parallel to the above-mentioned axis and that interconnect the above-mentioned substructures **42***a-c*; sheet of flexible leaflet material **160** having a central opening **150** with three sides **61**; leaflet-linking areas **180**; the sheet **160** continues radially outwardly beyond at least a portion of at least one of the secured line portions **250** to form a flap **240/270**; a plurality of members disposed in a zig-zag pattern, e.g., **42***c*, that extends in a direction that is annular of the supporting structure; at least two of the members (e.g., the two members that meet at **440**) meeting at an apex **440** that points away from the supporting structure parallel to an axis about which the supporting structure is annular; a sheet of flexible material **70** and/or **80** secured to the supporting structure; a plurality of flexible leaflets **60/160**; suture attachment **90** at the apex **440**; the apex **440** includes an eyelet **21**; an enlarged head **450** on the end of a reduced neck **452**; a notch **460**; the notch is narrowed near its entrance **462**. The examples for certain claim terms provided in this paragraph are only illustrative. As just one example of this, not all of the reference numbers that are used for certain features and elements in certain FIGS. are repeated in every FIG. for every reoccurrence of the same or similar features or elements.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number of cells employed in the stents in valves in accordance with the invention can be different from the numbers shown in the various illustrative embodiment described above.

What is claimed is:

1. A prosthetic heart valve comprising:

an annularly collapsible and re-expandable supporting structure extending between an inflow end and an outflow end;

a plurality of leaflets disposed inside the supporting structure; and

a lower skirt disposed adjacent the inflow end of the supporting structure, the lower skirt including a single continuous sheet that extends from a luminal surface of the supporting structure, wraps around the inflow end and extends over a portion of the abluminal surface of the supporting structure, wherein the lower skirt includes a first portion disposed on the luminal surface of the supporting structure and a second portion disposed on the abluminal surface of the supporting structure and the first portion and the second portion are coupled together at a top edge of the second portion.

2. A prosthetic heart valve comprising:

an annularly collapsible and re-expandable supporting structure extending between an inflow end and an outflow end;

a plurality of leaflets disposed inside the supporting structure; and

a lower skirt disposed adjacent the inflow end of the supporting structure, the lower skirt including a single continuous sheet that extends from a luminal surface of the supporting structure, wraps around the inflow end and extends over a portion of the abluminal surface of the supporting structure, the lower skirt including a first portion disposed on the luminal surface of the supporting structure and a second portion disposed on the abluminal surface of the supporting structure;

wherein the first portion and the second portion are sutured together at a top edge of the second portion.

3. A prosthetic heart valve comprising:

an annularly collapsible and re-expandable supporting structure extending between an inflow end and an outflow end;

a plurality of leaflets disposed inside the supporting structure; and

a lower skirt disposed adjacent the inflow end of the supporting structure, the lower skirt including a single continuous sheet that extends from a luminal surface of the supporting structure, wraps around the inflow end and extends over a portion of the abluminal surface of the supporting structure, the lower skirt including a first portion disposed on the luminal surface of the supporting structure and a second portion disposed on the abluminal surface of the supporting structure;

wherein the supporting structure includes a plurality of cells arranged in rows and the second portion extends over at least a portion of one of the plurality of cells.

4. The valve defined in claim **3**, wherein the plurality of flexible leaflets includes three leaflets.

5. The valve defined in claim **3**, wherein the supporting structure includes a stent formed of a plurality of struts.

6. The valve defined in claim **3**, wherein the lower skirt comprises a fabric.

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